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Description

Background and Description of the Invention

The present invention generally relates to endoprosthesis devices, in particular to a radially expandable endoprosthesis to a procedure for making same, and to a system comprising such an endoprosthesis. More particularly, the invention relates to a radially expandable endoprosthesis according to the preamble of Claim 1. Such an endoprosthesis is known e.g. from US-A-4 580 568. Such a generally tubular endoprosthesis is radially expandable between a generally unexpanded insertion circumference and an expanded implantation circumference which is greater than the unexpanded insertion circumference. Included are a plurality of generally circumferential sections, one or more of which includes one or more expandable segments that are bendable members which are generally collapsed when the endoprosthesis is in its generally unexpanded insertion orientation and which are generally opened when the endoprosthesis is in its expanded implantation orientation.

Endoprostheses are known for treating stenoses, aneurysm conditions and the like. An endoprosthesis device of this type, which is at times referred to as a stent, is typically placed or implanted by a mechanical transluminal procedure. Often a device of this type is percutaneously implanted within the vascular system to reinforce collapsing, partially occluded, weakened or abnormally dilated localized sections of a blood vessel or the like. When endoprostheses or stents are used to treat a stenosis condition, typically such is done in association with a dilation element such as an angioplasty balloon. In this instance, the dilation element or balloon device opens the constriction, and a stent or the like is positioned thereat in order to prevent or at least substantially slow re-formation of the stenosis.

One attribute of a stent is that it is radially compressible and expandable so that it will easily pass through a blood vessel or the like when collapsed and will expand to its implanted size after the stenosis, aneurysm or the like has been reached. It is also desirable that a stent be generally flexible throughout its length so that it is easily maneuverable through bends and curves of the blood vessel or the like. It is typically desirable that a stent or endoprosthesis have a substantial amount of open space so as to allow for endothelialization along its length and to minimize interference with collateral blood vessels and the like. While it is important that a stent or endoprosthesis lodge securely into place at the desired location, it can be advantageous to have a stent that is removable through a transluminal percutaneous procedure, should removal be needed.

Various currently known stent products have structures that are essentially coiled springs. When this type of spring stent is tightly coiled, its diameter is relatively small for insertion through a blood vessel or the like. When the coil is sprung or coiled more loosely, the stent assumes its expanded, implantation orientation. Maass et al U.S. Patent No. 4,553,545 is illustrative of this type of coiled spring stent or endoprosthesis. Multihelix or braided stents are also known, and they suffer from poor maneuverability. They are also difficult to remove once implanted, and they may exhibit numerous exposed, relatively sharp or jagged ends. Palmaz U.S. Patent No. 4,733,665 is representative of an expandable stent of this general type. Gianturco U.S. Patent No. 4,580,568 illustrates a percutaneous endovascular stent formed of stainless steel wire that is arranged in a closed zig-zag pattern somewhat in the nature of a bookbinder spring. Such a structure is somewhat unsymmetrical, and it may be subject to reocclusion due to the very large open space that is typically present between the wires of this type of device. Another type of stent is known as a Statz stent, and it includes a hypodermic tube with longitudinal slots etched into its body. While such a device has a high ratio of unexpanded to expanded diameter, it is a comparatively rigid device which is difficult to maneuver through a tortuous path and is not easily removed in a transluminal manner.

With many of these currently known stent structures, the axial length of the stent decreases as the circumference of the stent increases, which is typically a disadvantage. For example, any such length reduction must be taken into consideration in selecting proper stent sizing for a particular implantation procedure. Also, this attribute of many prior stents requires the passage through the blood vessel or the like of a stent which is longer than the length actually needed for the implantation procedure being performed. This is a particularly difficult problem for procedures in which the stent must be passed through a pathway having twists or turns, especially for a stent structure that is not easily bendable.

EP-A-0 282 175, published on September 14, 1988 i.e. after the priority date of the present application discloses a stent comprising a wire formed into a serpentine configuration including a series of straight sections and a plurality of bends. The free ends of said stent are not engaged with adjacent ones.

US-A-4,580,568 discloses a stent comprising a wire formed into a closed zig-zag configuration including an endless series of straigth sections, a plurality of bends, wherein said straigth sections

are joined by said bends to form the stent. In Fig. 7 and 8 of US-A-4,580,568 no free ends of the stent are shown.

US-A-4,665,918 discloses a prosthesis for insertion in a cavity of a human body comprising a cylinder of resilient expandible material in the form of a helical coil of an elastomeric material.

EP-A-0 212 852, published on April 28, 1989 i.e. after the priority date of this application, discloses a radially expandible vesicular stent of the type formed of wire wound generally in a helix, characterized by bends in the wire outside this helical path, which straightens as the stent is expanded. The stent has free ends which are curled into tight loops and do not engage any adjacent free end.

The present invention avoids the various deficiencies of these types of prior art structures and provides important and advantageous features of endoprostheses or stents.

A subject-matter of the present invention is a radially expandible endoprosthesis as defined in claim 1. Preferred embodiments thereof are subject-matter of claims 2 to 8. Another subject-matter of the present invention is a method for making a radially expandible endoprosthesis as defined in claim 9. Preferred embodiments thereof are subject-matter of claims 10 to 14. Another subject-matter of the present invention is an implantable and explantable endoprosthesis system as defined in claim 15. Preferred embodiments thereof are subject-matter of claims 16-19.

It is a general object of the present invention to provide an improved radially expandable, axially extending endoprosthesis of the type that can be transluminally implanted.

Another object of the present invention is to provide an improved endoprosthesis or stent that can be constructed to have very large radial expansion capabilities.

Another object of this invention is to provide an improved radially expandable axially extending endoprosthesis that is extremely maneuverable and capable of moving through a tortuous path.

Another object of the present invention is to provide an improved radially expandable axially extending endoprosthesis that can, if desired, be transluminally explanted by means of, for example, a snare lead or catheter.

Another object of the present invention is to provide an improved radially expandable axially extending endoprosthesis which includes members that can be spaced apart in a manner that enhances lodging of the endoprosthesis at its implanted site.

Another object of the present invention is to provide an improved axially extending endoprosthesis that can be constructed in order to be radially expandable by an expanding member or balloon of a catheter device and/or can be radially expandable due to spring-like properties of the endoprosthesis.

Another object of this invention is to provide an improved procedure for making an axially extending and/or generally tubular endoprosthesis that is radially expandable.

Another object of the present invention is to provide an improved system comprising an axially extending radially expandable endoprosthesis or stent and a device for transluminally explanting said endoprosthesis.

Another object of the present invention is to provide an improved radially expandable endoprosthesis that substantially avoids the presentation of any frayed edges and that generally maintains its axial length throughout various radial expansion positions.

These and other objects, features and advantages of this invention will be clearly understood through a consideration of the following detailed description.

Brief Description of the Drawings

In the course of this description, reference will be made to the attached drawings, wherein:

Figure 1 is a perspective view illustrating an early step in the procedure of making an endoprosthesis according to the present invention;

Figure 2 is an elevational view illustrating a step subsequent to that shown in Figure 1;

Figure 3 is an elevational view showing a manufacturing step subsequent to that of Figure 2, while also illustrating a substantially completed endoprosthesis in accordance with the present invention;

Figure 4 is a cross-sectional view along the line 4-4 of Figure 3;

Figure 5 is an enlarged detail view of a portion of one end of the endoprosthesis shown in Figure 3;

Figure 6 is a perspective view illustrating an early step in the procedure of making another embodiment of the endoprosthesis;

Figure 7 is an elevational view illustrating a step subsequent to that shown in Figure 6, while also illustrating the configuration of a portion of this endoprosthesis prior to its circumferential orientation;

Figure 8 is a perspective view illustrating an early step in the procedure of making a further embodiment of the endoprosthesis;

Figure 9 is an elevational view illustrating a step subsequent to that shown in Figure 8, while also illustrating the configuration of a portion of this endoprosthesis prior to its circumferential ori-

entation;
Figure 10 is an elevational view of an early step in the manufacturing procedure for still a further embodiment of the endoprosthesis;
Figure 11 is an elevational view of a step subsequent to that shown in Figure 10;
Figure 12 is an elevational view of a manufacturing step subsequent to that illustrated in Figure 11 and which shows a length of material suitable for winding on a mandrel in a generally helical manner in order to form the endoprosthesis of this embodiment;
Figure 13 is a generally cross-sectional view illustrating an early step in a procedure for implanting an endoprosthesis according to the present invention, this particular procedure being especially suitable for an endoprosthesis having spring-like properties;
Figure 14 is a generally cross-sectional view illustrating an implantation step subsequent to that shown in Figure 13;
Figure 15 is a generally cross-sectional view illustrating an implantation step subsequent to that of Figure 14;
Figure 16 is a generally cross-sectional view illustrating an implantation step subsequent to that illustrated in Figure 15;
Figure 17 is a generally cross-sectional view of an implantation step subsequent to that illustrated in Figure 16;
Figure 18 is a generally cross-sectional view of an implanted stent or endoprosthesis in accordance with the present invention;
Figure 19 is an elevational view of an endoprosthesis and distal end of a balloon catheter for an implantation procedure that is especially suitable for an endoprosthesis according to the present invention that is constructed of a malleable-type of material;
Figure 20 is a generally cross-sectional illustration of the endoprosthesis and catheter of Figure 19 positioned within a blood vessel;
Figure 21 is a generally cross-sectional illustration of an implantation stage subsequent to that shown in Figure 20;
Figure 22 is a generally cross-sectional illustration of an implantation stage subsequent to that shown in Figure 21;
Figure 23 is a generally cross-sectional illustration of an implanted stent or endoprosthesis according to the present invention;
Figure 24 is a generally cross-sectional illustration of a snare catheter shown explanting a stent or endoprosthesis in accordance with the present invention; and
Figure 25 is a generally cross-sectional illustration showing a further stage of the explantation procedure illustrated in Figure 24.

Description of the Particular Embodiments

A radially expandable axially extending endoprosthesis or stent is generally designated as 31 in Figure 3, as well as in Figure 4. The stent includes a plurality of generally circumferential sections 32. In this illustrated embodiment, each of the circumferential sections 32 are formed from the same continuous, helically wrapped length, such as the undulating length 33 shown in Figure 2.

At least one of the circumferential sections 32 includes at least one expandable segment 34. Expandable segment 34 is a bendable member that typically includes one or more legs 35. Each leg 35 is bendably secured to the rest of the circumferential section 32 by a so-called living joint or hinge that is a unitary or integral component of the leg 35 and the adjacent portion of the circumferential section 32. For example, in the embodiment illustrated in Figures 1 through 5, each leg 35 is bendably joined to another leg 35 through an integral or living hinge 36 which has a generally arcuate shape. When the stent 31 expands, the integral hinge 36 permits end portions 37 of the legs 35 to move farther apart, thereby increasing the circumference and diameter of the stent 31. Of course, the circumference and diameter of the stent 31 can be reduced by forces which move these end portions 37 closer to each other.

An understanding of the manner in which the endoprostheses according to this invention, such as the stent 31, can be made will be obtained from a consideration of Figures 1, 2 and 3. Figure 1 shows a mandrel 38 that has a cross-sectional configuration that is somewhat oval in shape. Mandrel 38 can, for example, be a circular tube that has been flattened on two opposing longitudinal portions in order to provide a cross-section that is generally rectangular in shape, with two opposing end portions thereof being arcuate or rounded. A strand 39 of wire or other material, as generally discussed elsewhere herein, is generally tightly wound over the mandrel to the extent that the strand 39 takes on a cross-sectional shape along the lines of that of the mandrel 38. Preferably, this winding is done in a manner such that there is a substantial spacing between each individual wind of the strand 39. Generally speaking, the tighter the wind and the thinner the mandrel, the closer will be the spacing between the expandable segments 34 of the completed stent 31.

After this winding procedure has been completed, the mandrel 38 is removed from the wound strand 39. The wound strand 39 is then subjected to flattening forces so that the three-dimensional wound strand 39 is transformed into a generally planar shape such as that of the undulating length 33 shown in Figure 2. These forces may be applied

by any suitable means. For example, the wound strand 39 can be compressed between two planar surfaces, during which procedure, portions of the wound strand 39 are twisted until the generally uniplanar undulating length 33 is formed. This length has a generally sinusoidal character.

In order to complete formation of the stent 31 illustrated in Figure 3, the undulating length 33 is then wound, in a generally helical manner, around a substantially cylindrical mandrel 41, as is generally illustrated in Figure 3. This generally helical wrapping procedure continues until the desired number of circumferential sections are formed in order to provide a stent 31 of a desired length.

With reference to Figure 5, this winding procedure that is generally illustrated in Figure 3 includes proceeding in a manner so as to avoid the presentation of any loose ends in the completed stent 31. This is readily accomplished by forming the strand 39 and the undulating length 33 so that each end circumferential section 42 has a free end 43 that readily hooks onto an adjacent portion of the stent 31, such as an integral hinge 36 of the circumferential section 32 that is adjacent to and inwardly spaced from the end circumferential section 42. The free end 43 illustrated in Figure 5 is in the nature of a hook portion that readily loops or tucks into the integral hinge 36.

Regarding the embodiment shown in Figures 6 and 7, the mandrel around which the strand 39 is wound is a substantially rectangular mandrel 44. As a result, the generally planar structure that is subsequently formed is an undulating length 45 that includes a plurality of legs 46 joined by a unitary or integral hinge or living hinge 47 that is typically less arcuate than the integral hinge 36. This undulating length 45 is then formed into an endoprosthesis or stent by helically winding same on a structure such as the cylindrical mandrel 41.

Another embodiment of the endoprosthesis or stent is made in a manner generally illustrated in Figures 8 and 9. Here, the mandrel is a generally lens-shaped mandrel 51 which has a transverse cross-section that can be described as defining two convex surfaces positioned in back-to-back relationship with each other. Much in the same manner as the other embodiments, the elongated strand 39 is wound around the lens-shaped mandrel 51. The mandrel 51 is subsequently moved therefrom, and the wound strand 39 is rendered substantially uniplanar in order to form undulating length 52 that is suitable for forming into a stent by wrapping around the mandrel 41.

Another embodiment illustrating the manufacture of an endoprosthesis or stent in accordance with this invention is generally illustrated in Figures 10, 11 and 12. A strand is wound around a small-diameter mandrel 53. In this case, the strand is formed into a tightly wound helix 54. Thereafter, the mandrel 53 is removed, and the strand is formed into a more loosely wound helix 55. For example, the helix 55 can be elongated such that the pitch angle is less than approximately 60°. This helix 55 is then flattened generally in the manner previously discussed, for example to 15.000 kg (15 tons) in a pneumatic press, in order to form a generally uni-planar undulating length 56. If desired, the length 56 can be axially compressed in a contained mold to the desired pitch angle. Length 56 is suitable for winding around cylindrical mandrel 41 in order to thereby form an endoprosthesis or stent.

Stents illustrated herein are typically capable of moving through a tortuous path that may be encountered in vascular system implantation. Such stents can be easily axially bent over a relatively small radius without damage or high bending resistance.

It should be appreciated that in the illustrated embodiments, each circumferential section 32 is generally identical. It is also possible within the spirit of the invention to provide circumferential sections that are not this uniformly shaped. For example, the circumference of adjacent sections can differ in order to form a stent that is not strictly shaped in the nature of a right cylinder. For example, tapered, truncated cone-shaped stents or stepped stents can be provided. In addition, in some applications, it can be suitable to include circumferential sections that are not composed entirely of expandable segments, but instead could include non-expandable portions that are joined by expandable segments. It also may be possible to provide stents within the spirit of the present invention which include one or more circumferential sections that form a stent device without proceeding with helical winding around cylindrical mandrel 41 or the like. It is also possible to provide a stent that has a generally bifurcated structure for use in situations in which the stenosis, aneurysm or the like that is to be treated is at a branching location within the vascular system or the like. Such a bifurcated stent structure can be formed, for example, by joining portions of the opposing ends of two different unitary stents in order to provide a total structure that is bifurcated, Y-shaped or the like.

The materials out of which stents according to the present invention can be made, and especially the expandable segments thereof, fall into two general categories. The material can be either elastic or generally inelastic. Examples of elastic materials include spring steels, stainless steel, Nitinol®, Elgiloy®, an alloy known as NP36N, and the like. Generally inelastic materials can be characterized as being malleable. Included are tantalum, titanium, silver, gold, and annealed versions of the elastic

materials described herein. Polymers may also be used, such as polyether sulfone, polyimide, polycarbonate, polypropylene, ultra high molecular weight polyethylene, carbon fiber, Kevlar®, and the like. It is also possible to coat these materials with porous or textured surfaces for cellular ingrowth and the like or with non-thrombogenic agents such as pyrolytic carbon, heparin, hydrogels, Teflon materials, silicones, polyurethanes and the like. The stents can be treated so that drugs can be eluted therefrom. It is also possible that certain stents may be made of biodegradable materials. In any event, the stent material, of course, is to be biocompatible.

Figures 13 through 18 illustrate an implantation procedure and an insertion system that is particularly suitable for stents that are constructed of an elastic material such as spring steel. A stenosis or lesion 61 is shown within a blood vessel 62. The stent 31 is positioned on a balloon catheter, generally designated as 63. An introducer tube or plunger 64, or a similar stop-providing structure, is positioned along the outside surface of the catheter tube 65. The stent 31 is located distally of the member 64, and a sheath 66 holds the stent 31 in a generally compressed state during which the expandable segments of the stent 31 are generally collapsed or closed. Figure 13 further shows the balloon 67 of the catheter in a mode in which it is exerting outwardly radially directed forces on the lesions in order to dilate same to provide a wider opening as generally illustrated in Figure 14 in order to thereby generally reduce the overall extent of the lesion 61a. At this time, the balloon 67 is collapsed, and the catheter 63 is moved in a distal direction so that the collapsed stent 31 is generally positioned within the lesion 61a. Next, as illustrated in Figure 15, the sheath 66 is withdrawn by moving same in a generally proximal direction, and the stent 31 is released from the sheath 66. This release can be such that adjacent circumferential sections of the stent expand in a generally sequential manner, which is generally illustrated in Figure 15.

After this procedure is completed, the entire stent 31 has been sprung, and it springingly engages the dilated lesion 61a, which is generally illustrated in Figure 16. Thereafter, as seen in Figure 17, the catheter 63 can be moved in a generally proximal direction until the balloon 67 is again generally aligned with the dilated lesion 61a, as desired. Then, the balloon 67 can be pressurized in order to further implant the stent 31 and in order to further dilate the lesion as desired so as to form a treated lesion 61b which remains after the catheter 63 is removed, as is generally shown in Figure 18.

Figures 19 through 23 show an arrangement that is especially suitable for non-elastic stents in which the expandable segments thereof are made of malleable material. With reference to Figures 19 and 20, a stenosis or lesion 61 within blood vessel 62 is transluminally reached by a balloon catheter 71 having a stent 31 overlying the collapsed balloon 72 of the catheter 71. The balloon 72 is then expanded in a well-known manner, at which time the stent 31 is also expanded by opening the expandable segments thereof. An intermediate dilation position is shown in Figure 21, and an initially dilated lesion 61a is shown therein. Figure 22 shows additional dilation by the balloon 72, and the thus treated lesion 61b is also shown. After this stage is achieved, the balloon catheter 71 is removed, as shown in Figure 23.

The stent 31 remains in place as generally illustrated in Figure 23 because the malleable material (or for that matter an elastic material) exerts a hoop stress when it is expanded to the size illustrated in Figure 23 such that it will not collapse by inwardly directed radial forces presented by the treated lesion and vessel wall or the like. In other words, the hoop stress of the expanded stent is greater than the hoop forces exerted by the passageway within which the stent is implanted. In addition, the force required to open the collapsed stent by the balloon is less than the hoop force provided by. the balloon. In other words, the hoop stress of the collapsed or unextended stent is less than that of the hoop force provided by the pressurized balloon of the catheter. One feature that can contribute to the advantageous hoop stress properties of the malleable stents of the type illustrated in the drawings is the ability of the stent to expand well beyond that needed to effect the dilation procedure. For example, a typical dilation procedure and stent extension is one in which the fully extended dilating diameter or circumference is approximately three times the insertion or collapsed diameter or circumference. With stent structures such as those illustrated in the drawings, the amount of possible expansion can be on the order of twelve times. This feature, together with the malleability of the particular material utilized, tends to reduce the hoop force that is needed to expand the stent to about three times its insertion or collapsed configuration.

Figures 24 and 25 illustrate a stent withdrawal procedure and a snare catheter system that can be used to remove or explant implanted stents according to the present invention. A snare catheter, generally designated as 74, is illustrated. An elongated member 75 is slidably positioned within a catheter body 76. Elongated member 75 includes a hook member 77 at its distal end. When extended into the stent 31, the hook member 77 snares a portion

of the stent 31. A suitable control structure, such as the puller assembly 78 illustrated is manipulated in order that the hook member moves in a proximal direction, with the result that the stent begins to uncoil and is opened to such an extent that it can be passed through the blood vessel 62 or the like until it is totally removed from the body by continued movement of the elongated member 75 in the proximal direction.

For purposes of illustration, the following details are given regarding a typical stent 31. An exemplary malleable material is tantalum wire having a diameter of 0.013 cm (0.005 inch) wound on a mandrel having a nominal diameter of 0.051 cm (0.020 inch). The length of each leg 46 is on the order of about 0.122 cm (0.048 inch), and the center-to-center spacing between adjacent integral or living hinges 36 is about 0.107 cm (0.042 inch). A typical collapsed or insertion outer diameter for such a stent is about 0.216 cm (0.085 inch), with the inner diameter thereof being about 0.178 cm (0.070 inch). The overall length of the stent 31 is selected to be that generally needed to treat the lesion or the like inasmuch as the overall length of the stent will remain substantially the same whether it is collapsed or extended, except to the degree that the legs 46 of the exterior circumferential sections 32 move somewhat inwardly as the hinge is flexed, thereby somewhat nominally decreasing the overall length of the stent.

Claims

1. A radially expandable endoprosthesis, comprising:

a plurality of generally circumferential sections (32), said generally circumferential sections being substantially adjacent to one another and generally axially oriented with respect to each other in order to thereby generally define an endoprosthesis (31);

at least one of said generally circumferential sections includes an expandable segment (34) that imparts radial expandability to said generally circumferential section whereby said section has an unexpanded insertion circumference and an expanded implantation circumference which is greater than said unexpanded insertion circumference; and

said expandable segment of the generally circumferential section is a generally foldable member that is bendable between a generally closed orientation and a generally opened orientation so as to impart radial expandability, to the generally circumferential section (32), characterized in that an outside one of said generally circumferential sections has a free end (43) engaged with an adjacent one of said generally circumferential sections.

2. The endoprosthesis according to claim 1, wherein said foldable member includes a generally elbow-like member that is a living hinge (36) unitarily connecting a pair of legs (35), and said generally circumferential sections form a substantially cylindrical endoprosthesis.

3. The endoprosthesis according to claim 1 or 2, wherein said free end (43) has hook means (43) for engaging an adjacent one of said generally circumferential sections (32).

4. The endoprosthesis according to claim 1, 2 or 3 wherein said expandable segment is a generally foldable elastic spring-like member, and wherein the unexpanded insertion circumference of the endoprosthesis is maintained by an overlying sheath (66).

5. The endoprosthesis according to claim 1, 2 or 3, wherein said expandable segment is a generally foldable malleable member, and wherein the expanded implantation circumference is achieved by radially directed forces from an expandable element (72) of a catheter (71).

6. The endoprosthesis according to any of claims 1-5, wherein said generally foldable member (52, 56) is substantially V-shaped.

7. The endoprosthesis according to any of claims 1-6, wherein said endoprosthesis is generally tubular, and respective circumferential edges of respective generally circumferential sections are generally adjacent to each other.

8. The endoprosthesis according to any of claims 1-7, wherein said expandable segment of the generally circumferential section had been formed by a process including winding a strand (39) on a shaped mandrel (38, 44, 51, 53) to form a wound strand which was subsequently flattened to a generally uni-planar configuration (33, 45, 52, 56).

9. A method for making a radially expandable endoprosthesis, comprising:

selecting a mandrel (38, 44, 51, 53) having a relatively small cross-sectional area in order to provide a narrow wrapping surface;

winding an elongated strand (39) around said narrow wrapping surface and removing the strand from said small mandrel so as to form a wound strand having a plurality of turns therein, said turns being shaped to generally conform to the shape of said cross-sectional

area;

subjecting said wound strand to flattening forces in order to form a generally uni-planar undulating strand length (33, 45, 52, 56);

providing another mandrel (41) having a cross-sectional area greater than that of said relatively small mandrel;

generally helically wrapping said undulating strand length around said another mandrel and removing said another mandrel to thereby provide a radially expandable endoprosthesis (31); and

engaging a free end (43) of said undulating strand length with an adjacent portion of said undulating strand length after said generally helically wrapping step has been initiated, thereby avoiding the presentation of loose ends on the endoprosthesis.

10. The method according to claim 9 , wherein said providing step includes selecting the another mandrel to have a generally cylindrical outer surface.

11. The method according to claim 9 or 10 , wherein said selecting step includes choosing the relatively small mandrel (38) so that the wrapping surface is generally oval in shape.

12. The method according to claim 9 or 10 , wherein said selecting step includes choosing the relatively small mandrel (44) so that the wrapping surface is generally rectangular in shape.

13. The method according to claim 9 or 10 , wherein said selecting step includes choosing the relatively small mandrel (51) so that the wrapping surface is generally lens-shaped in shape.

14. The method according to claim 9 or 10 , wherein said selecting step includes choosing the relatively small mandrel (53) so that the wrapping surface is generally circular in shape.

15. An implantable and explantable endoprosthesis system, comprising a radially expandable axially extending endoprosthesis (31) and a device (74) for transluminally explanting the endoprosthesis; said endoprosthesis includes:

a plurality of generally circumferential sections (32), said generally circumferential sections being substantially adjacent to one another and generally axially oriented with respect to each other in order to thereby generally define an endoprosthesis,

at least one of said generally circumferential sections includes an expandable segment (34) that imparts radial expandability to said generally circumferential section whereby said section has an unexpanded insertion circumference and an expanded implantation circumference which is greater than said unexpanded insertion circumference, and

said expandable segment of the generally circumferential section is a generally foldable member that is bendable between a generally closed orientation and a generally opened orientation so as to impart radial expandability to the generally circumferential section (32); characterized in that an outside one of said generally circumferential sections has a free end (43) engaged with an adjacent one of said generally circumferential sections; and

in that said device for transluminally explanting the endoprosthesis includes:

an elongated member (75) that is percutaneously insertable into a blood vessel (62) or the like within which said endoprosthesis has been radially expanded and implanted, said elongated member having a proximal portion exterior of the body,

snaring means (77) at a distal end of the elongated member,

means for manipulating a proximal portion of the elongated member from a location exterior of the body, said manipulating means facilitating engagement of said snaring means with one of said circumferential sections of the implanted endoprosthesis,

puller means (78) for sliding the elongated member in a proximal direction by moving the body-exterior proximal portion of the elongated member in a direction away from the endoprosthesis,

said puller means further being for reducing the radial size of the endoprosthesis to less than said expanded implantation circumference and such that it will pass through the blood vessel or the like, and

means for completely removing the elongated member from the body until the endoprosthesis of reduced radial size has been fully explanted.

16. The system according to claim 15 , wherein said generally circumferential sections form a continuous helix that defines the axially extending endoprosthesis, and wherein said puller means is for at least partially uncoiling said helix.

17. The system according to claim 15 , wherein said puller means is for uncoiling the endoprosthesis being explanted.

18. The system according to claim 15, 16 or 17, further including a catheter body (76) within which said elongated member is slidably mounted.

19. The system according to claim 15, 16, 17 or 18, wherein said snaring means includes a hook member.

Patentansprüche

1. Radial ausdehnbare Endoprothese, umfassend: eine Mehrzahl von im allgemeinen umfangsmäßigen Bereichen (32), wobei die im allgemeinen umfangsmäßigen Bereiche im wesentlichen einander benachbart sind und in Bezug zueinander im allgemeinen axial ausgerichtet sind, um dadurch im allgemeinen eine Endoprothese (31) zu bilden;

wobei mindestens einer der im allgemeinen umfangsmäßigen Bereiche ein ausdehnbares Segment (34) umfaßt, welches dem im allgemeinen umfangsmäßigen Bereich eine radiale Ausdehnbarkeit verleiht, wobei der Bereich einen nicht ausgedehnten Einführungsumfang und einen ausgedehnten Implantationsumfang, der größer als der nicht ausgedehnte Einführungsumfang ist, umfaßt, und worin

das ausdehnbare Segment des im allgemeinen umfangsmäßigen Bereichs ein im allgemeinen faltbares Element ist, das biegbar zwischen einer im allgemeinen geschlossenen Ausrichtung und einer im allgemeinen geöffneten Ausrichtung ist, um dem im allgemeinen umfangsmäßigen Bereich (32) eine radiale Ausdehnbarkeit zu verleihen, dadurch gekennzeichnet, daß ein außenseitiger der im allgemeinen umfangsmäßigen Bereiche ein freies Ende (43) hat, das im Eingriff mit einem benachbarten der im allgemeinen umfangsmäßigen Bereiche ist.

2. Endoprothese nach Anspruch 1, worin das faltbare Element ein im allgemeinen ellbogenartiges Element umfaßt, das eine lebende Verbindung (36) ist, die ein Paar von Schenkeln (35) zu einer Einheit verbindet und worin die im allgemeinen umfangsmäßigen Bereiche eine im wesentlichen zylindrische Endoprothese bilden.

3. Endoprothese nach Anspruch 1 oder 2, worin das freie Ende (43) Hakenmittel (43) zum Eingreifen in einen der benachbarten im allgemeinen umfangsmäßigen Bereiche (32) aufweist.

4. Endoprothese nach Anspruch 1, 2 oder 3, worin das ausdehnbare Segment ein im allgemeinen faltbares elastisches federartiges Element ist und worin der nicht ausgedehnte Einführungsumfang der Endoprothese durch eine darüberliegende Hülle (66) aufrechterhalten wird.

5. Endoprothese nach Anspruch 1, 2 oder 3, worin das ausdehnbare Segment ein im allgemeinen faltbares, verformbares Element ist und worin der ausgedehnte Implantationsumfang durch radial gerichtete Kräfte von einem expandierbaren Element (72) eines Katheters (71) erreicht wird.

6. Endoprothese nach einem der Ansprüche 1 bis 5, worin das im allgemeinen faltbare Element (52,56) im wesentlichen V-förmig ist.

7. Endoprothese nach einem der Ansprüche 1 bis 6, worin die Endoprothese im allgemeinen rohrförmig ist und entsprechende umfangsmäßige Ränder entsprechender im allgemeinen umfangsmäßiger Bereiche im allgemeinen einander benachbart sind.

8. Endoprothese nach einem der Ansprüche 1 bis 7, worin das ausdehnbare Segment des im allgemeinen umfangsmäßigen Bereichs durch ein Verfahren gebildet wurde, welches das Wickeln eines Strangs (39) auf einen geformten Dorn (38,44,51,53) umfaßt, um einen gewundenen Strang zu bilden, der nachfolgend zu einer im allgemeinen uniplanaren Konfiguration (33,45,52,56) abgeflacht wurde.

9. Verfahren zum Herstellen einer radial ausdehnbaren Endoprothese, umfassend:

Auswählen eines Dorns (38, 44, 51, 53) mit einem relativ kleinen Querschnitt, um eine enge Umhüllungsoberfläche vorzusehen,

Wickeln eines langgestreckten Strangs (39) um die enge Umhüllungsoberfläche und Entfernen des Strangs von dem kleinen Dorn, um einen gewundenen Strang mit einer Vielzahl von Windungen darin zu bilden, wobei die Windungen derart geformt sind, daß sie im allgemeinen mit der Form des Querschnitts übereinstimmen,

Unterwerfen des gewundenen Strangs unter Abflachungskräfte, um ein im allgemeinen uniplanares, wellenförmiges Strangstück (33,45,52,56) zu bilden,

Bereitstellen eines weiteren Dorns (41) mit einem Querschnitt, der größer als derjenige des relativ kleinen Dorns ist,

im allgemeinen helicales Wickeln des wel-

lenförmigen Strangstücks, um den weiteren Dorn und Entfernen des weiteren Dorns, um dadurch eine radial ausdehnbare Endoprothese (31) bereitzustellen und

in Eingriff bringen eines freien Endes (43) des wellenförmigen Strangstücks mit einem benachbarten Teil des wellenförmigen Strangstücks nachdem der im allgemeinen helicale Einwickelschritt begonnen wurde, wodurch das Vorliegen von losen Enden an der Endoprothese vermieden wird.

10. Verfahren nach Anspruch 9, worin der Bereitstellungsschritt umfaßt, daß der weitere Dorn eine im allgemeinen zylindrische, Außenfläche aufweist.

11. Verfahren nach Anspruch 9 oder 10, worin der Auswahlschritt ein Auswählen des relativ kleinen Dorns (38) umfaßt,sodaß die Umwicklungsoberfläche eine im allgemeinen ovale Form aufweist.

12. Verfahren nach Anspruch 9 oder 10, worin der Auswahlschritt ein Auswählen des relativ kleinen Dorns (44) umfaßt, sodaß die Umwicklungsoberfläche eine im allgemeinen rechteckige Form aufweist.

13. Verfahren nach Anspruch 9 oder 10, worin der Auswahlschritt ein Auswählen des relativ kleinen Dorns (51) umfaßt, sodaß die Umwicklungsoberfläche eine im allgemeinen linsenförmige Form aufweist.

14. Verfahren nach Anspruch 9 oder 10, worin der Auswahlschritt ein Auswählen des relativ kleinen Dorns (53) umfaßt,sodaß die Umwicklungsoberfläche eine im allgemeinen runde Form aufweist.

15. Implantierbares und explantierbares Endoprothesesystem, umfassend eine radial ausdehnbare, sich axial erstreckende Endoprothese (31) und eine Vorrichtung (74) zum transluminalen Explantieren der Endoprothese, wobei die Endoprothese umfaßt:

eine Mehrzahl von im allgemeinen umfangsmäßigen Bereichen (32), wobei die im allgemeinen umfangsmäßigen Bereiche im wesentlichen einander benachbart sind und in Bezug zueinander im allgemeinen axial ausgerichtet sind, um dadurch im allgemeinen eine Endoprothese zu bilden;

wobei mindestens einer der im allgemeinen umfangsmäßigen Bereiche ein ausdehnbares Segment (34) umfaßt, welches dem im allgemeinen umfangsmäßigen Bereich eine radiale Ausdehnbarkeit verleiht, wobei der Bereich einen nicht ausgedehnten Einführungsumfang und einen ausgedehnten Implantationsumfang, der größer als der nicht ausgedehnte Einführungsumfang ist, umfaßt, und worin

das ausdehnbare Segment des im allgemeinen umfangsmäßigen Bereichs ein im allgemeinen faltbares Element ist, das biegbar zwischen einer im allgemeinen geschlossenen Ausrichtung und einer im allgemeinen geöffneten Ausrichtung ist, um dem im allgemeinen umfangsmäßigen Bereich (32) eine radiale Ausdehnbarkeit zu verleihen, dadurch gekennzeichnet, daß ein außenseitiger der im allgemeinen umfangsmäßigen Bereiche ein freies Ende (43) hat, das im Eingriff mit einem benachbarten, der im allgemeinen umfangsmäßigen Bereiche ist, und daß die Vorrichtung zum transluminaren Explantieren der Endoprothese umfaßt:

ein langgestrecktes Element (75), das perkutan in ein Blutgefäß (62) oder dergleichen einschiebbar ist, innerhalb welchem die Endoprothese radial ausgedehnt und implantiert worden ist, wobei das langgestreckte Element einen proximalen Abschnitt außerhalb des Körpers hat,

Schlingenmittel (77) an einem distalen Ende des langgestreckten Elements,

Mittel zum Handhaben eines proximalen Abschnitts des langgestreckten Elements von einem außerhalb des Körpers gelegenen Ort aus, wobei die Handhabungsmittel das Eingreifen der Schlingenmittel in einen der umfangsmäßigen Bereiche der implantierten Endoprothese erleichtern,

Ziehmittel (78) zum gleitenden bewegen des langgestreckten Elements in eine proximale Richtung durch Bewegen des außerhalb des Körpers gelegenen proximalen Abschnitts, des langgestreckten Elements in eine Richtung weg von der Endoprothese,

wobei das Ziehmittel weiterhin zum Verringern der radialen Größe der Endoprothese auf eine kleinere Größe als der ausgedehnte Implantationsumfang und derart, daß sie durch das Blutgefäß oder dergleichen gelangen wird, dienen und

Mittel zum vollständigen Entfernen des langgestreckten Elements aus dem Körper bis die Endoprothese mit verringerter radialer Größe vollständig explantiert ist.

16. System nach Anspruch 15, worin die im allgemeinen umfangsmäßigen Bereiche eine kontinuierliche Helix bilden, welche die sich axial ausdehnende Endoprothese bildet und worin

das Ziehmittel dazu dient die Helix zumindest teilweise abzuwickeln.

17. System nach Anspruch 15, worin das Ziehmittel zum Abwickeln der zu explantierenden Endoprothese dient.

18. System nach Anspruch 15, 16 oder 17, weiterhin umfassend einen Katheterkörper (76), innerhalb welchem das langgestreckte Element verschiebbar angebracht ist.

19. System nach Anspruch 15, 16, 17 oder 18, worin das Schlingenmittel ein Hakenelement umfaßt.

Revendications

1. Endoprothèse radialement expansible, comprenant

une pluralité de sections généralement circonférentielles (32), ces sections généralement circonférentielles étant sensiblement contiguës entre elles et orientées généralement axialement l'une par rapport à l'autre pour définir ainsi de façon générale une endoprothèse (31);

au moins l'une des sections généralement circonférentielles comprend un segment expansible (34) qui confère une expansibilité radiale à la section généralement circonférentielle, cette section ayant une circonférence d'introduction non expansée et une circonférence d'implantation expansée qui est supérieure à la circonférence d'insertion non expansée ; et

le segment expansible de la section généralement circonférentielle est un élément généralement pliable entre une orientation généralement fermée et une orientation généralement ouverte de façon à conférer une expansibilité radiale à la section généralement circonférentielle (32), caractérisée en ce qu'une section extérieure des sections généralement circonférentielles présente une extrémité libre (43) coopérant avec une section adjacente des sections généralement circonférentielles.

2. Endoprothèse selon la revendication 1, dans laquelle l'élément pliable comprend un élément généralement en forme de coude qui est une articulation mobile (36) raccordant unitairement une paire de branches (35) et les sections généralement circonférentielles forment une endoprothèse sensiblement cylindrique.

3. Endoprothèse selon la revendication 1 ou 2, dans laquelle l'extrémité libre (43) présente un moyen de crochet (43) pour coopérer avec une section contigue des sections généralement circonférentielles (32).

4. Endoprothèse selon la revendication 1, 2 ou 3, dans laquelle le segment expansible est un élément de type ressort élastique généralement pliable et dans lequel la circonférence d'introduction non expansée de l'endoprothèse est maintenue par une gaine de recouvrement (66).

5. Endoprothèse selon la revendication 1, 2 ou 3, dans laquelle le segment expansible est un élément malléable généralement pliable et dans lequel la circonférence d'implantation expansée est obtenue par des forces dirigées radialement à partir d'un élément expansible (72) d'un cathéter (71).

6. Endoprothèse selon l'une quelconque des revendications 1-5, dans laquelle l'élément généralement pliable (52, 56) est sensiblement en forme de V.

7. Endoprothèse selon l'une quelconque des revendications 1-6, dans laquelle l'endoprothèse est en général tubulaire et les bords circonférentiels respectifs des sections généralement circonférentielles respectives sont généralement contiguës entre elles.

8. Endoprothèse selon l'une quelconque des revendications 1-7, dans laquelle le segment expansible de la section généralement circonférentielle a été formé par un procédé comprenant l'étape d'enroulement d'un fil (39) sur un mandrin formé (38, 44, 51, 53) pour former un fil enroulé qui a été ultérieurement aplati pour donner une configuration généralement uniplanaire (33, 45, 52, 56).

9. Procédé pour la fabrication d'une endoprothèse radialement expansible, comprenant les étapes consistant à :

choisir un mandrin (38, 44, 51, 53) de section transversale relativement petite pour fournir une surface d'enroulement étroite ;

enrouler un fil allongé (39) autour de la surface d'enroulement étroite et enlever le fil du petit mandrin de façon à former un fil enroulé ayant une pluralité de spires, ces spires étant formées de façon à s'adapter généralement à la forme de la section transversale ;

soumettre ce fil enroulé à des forces d'aplatissement pour former un tronçon de fil ondulant de façon générale uniplanaire (33, 45, 52, 56) ;

fournir un autre mandrin (41) ayant une

surface transversale supérieure à celle du mandrin relativement petit ;

enrouler de façon générale hélicoïdalement le tronçon de fil ondulant autour d'un autre mandrin en enlever l'autre mandrin pour fournir ainsi une endoprothèse radialement expansible (31) ; et

engager une extrémité libre (43) du tronçon de toron ondulant avec une portion contiguë du tronçon de fil ondulant après avoir commencé l'étape d'enroulement de façon généralement hélicoïdalement, évitant ainsi la présentation d'extrémités détachées sur l'endoprothèse.

10. Procédé selon la revendication 9, dans lequel l'étape consistant à prévoir le mandrin comporte la sélection de l'autre mandrin de surface extérieure généralement cylindrique.

11. Procédé selon la revendication 9 ou 10, dans lequel l'étape de sélection comprend le choix d'un mandrin relativement petit (38) de façon que la surface d'enroulement soit de forme généralement ovale.

12. Procédé selon la revendication 9 ou 10, dans lequel l'étape de sélection comprend le choix d'un mandrin relativement petit (44) de façon que la surface d'enroulement soit généralement de forme rectangulaire.

13. Procédé selon la revendication 9 ou 10, dans lequel l'étape de sélection comprend le choix d'un mandrin relativement petit (51) de façon que la surface d'enroulement est généralement de forme lenticulaire.

14. Procédé selon la revendication 9 ou 10, dans lequel l'étape de sélection comprend le choix d'un mandrin relativement petit (53) de sorte que la surface d'enroulement est généralement de forme circulaire.

15. Système d'endoprothèse implantable et explantable, comprenant une endoprothèse (31) s'étendant axialement expansible radialement et un dispositif (74) pour explanter transluminalement l'endoprothèse; l'endoprothèse comprend :

une pluralité de sections généralement circonférentielles (32), ces sections généralement circonférentielles étant sensiblement contiguës entre elles et orientées de façon générale axialement l'une par rapport à l'autre pour définir ainsi de façon générale une endoprothèse,

au moins l'une des sections généralement circonférentielles comprend un segment expansible (34) qui confère une expansibilité radiale à la section généralement circonférentielle, cette section ayant une circonférence d'introduction non expansée et une circonférence d'implantation expansée qui est supérieure à la circonférence d'introduction non expansée, et

le segment expansible de la section généralement circonférentielle est un élément généralement pliable qui peut être cintré entre une orientation généralement fermée et une orientation généralement ouverte de façon à conférer une expansibilité radiale à la section généralement circonférentielle (32) ; caractérisé en ce qu'une section extérieure parmi les sections généralement circonférentielles présente une extrémité libre (43) engagée par l'une des sections généralement circonférentielles contiguës ; et

en ce que le dispositif pour explanter transluminalement l'endoprothèse comprend :

un élément allongé (75) qui peut être introduit par voie percutanée dans un vaisseau sanguin (62) ou analogue dans lequel ladite endoprothèse a été radialement expansée et implantée, cet élément allongé ayant une portion proximale extérieure au corps,

des moyens de serre-noeud (77) sur l'extrémité distale de l'élément allongé,

des moyens pour manipuler une portion proximale de l'élément allongé à partir d'un emplacement extérieur au corps, ces moyens de manipulation facilitant l'engagement des moyens de serre-noeud avec l'une des sections circonférentielles de l'endoprothèse implantée,

des moyens d'extraction (78) pour faire coulisser l'élément allongé dans lune direction proximale en déplaçant la portion proximale extérieure au corps de l'élément allongé dans une direction l'éloignant de l'endoprothèse,

ce moyen d'extraction étant de plus destiné à réduire la taille radiale de l'endoprothèse à une taille inférieure à la circonférence d'implantation expansée et de façon à pouvoir passer à travers le vaisseau sanguin ou analogue, et

des moyens pour enlever entièrement l'élément allongé du corps jusqu'à ce que l'endoprothèse de taille radiale réduite ait été entièrement explantée.

16. Système selon la revendication 15, dans lequel les sections généralement circonférentielles forment une hélice continue qui définit l'endoprothèse s'étendant axialement et dans lequel le moyen d'extraction est destiné à dérouler cette hélice au moins partiellement.

17. Système selon la revendication 15, dans lequel le moyen d'extraction est destiné à dérouler l'endoprothèse explantée.

18. Système selon la revendication 15, 16 ou 17, comprenant de plus un corps de cathéter (76) à l'intérieur duquel est monté de façon coulissante l'élément allongé.

19. Système selon la revendication 15, 16, 17 ou 18, dans lequel les moyens de serre-noeud comprennent un élément de crochet.

FIG_1_

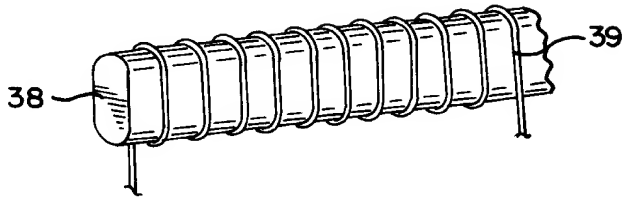


FIG_2_

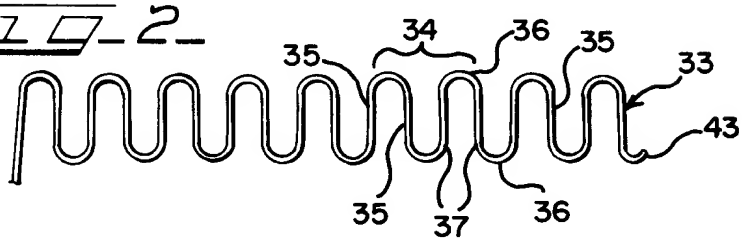


FIG_3_

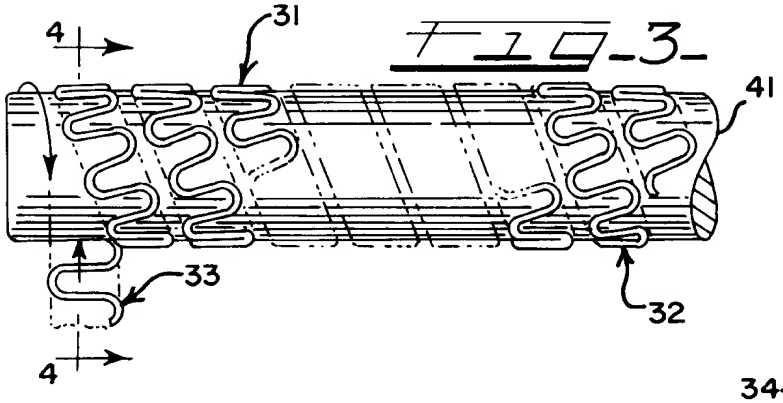


FIG_4_

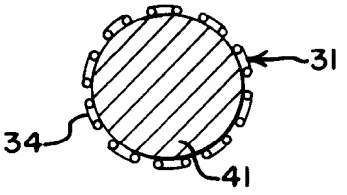


FIG_5_

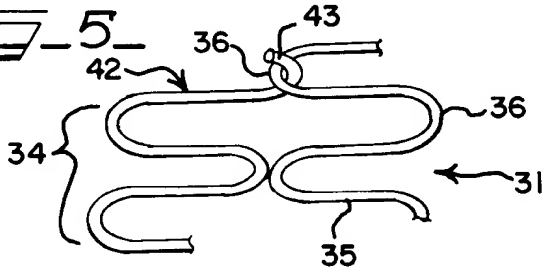


FIG_6_

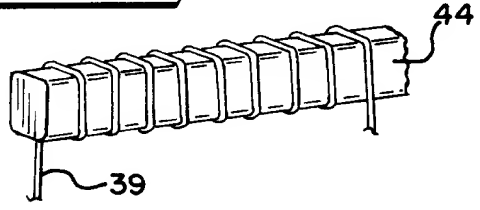


FIG_7_

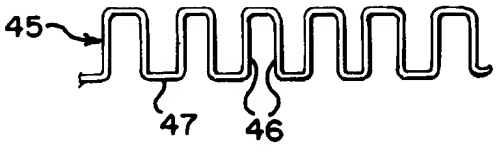


FIG. 8

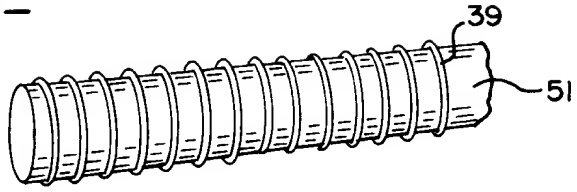


FIG. 9

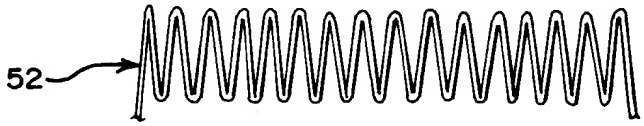


FIG. 10

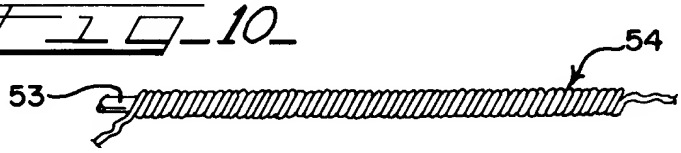


FIG. 11

FIG. 12

FIG. 13

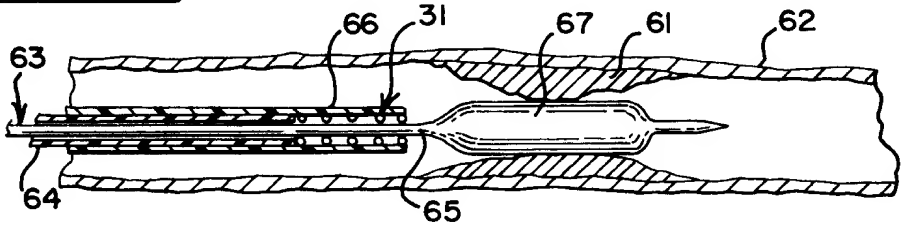


FIG. 14

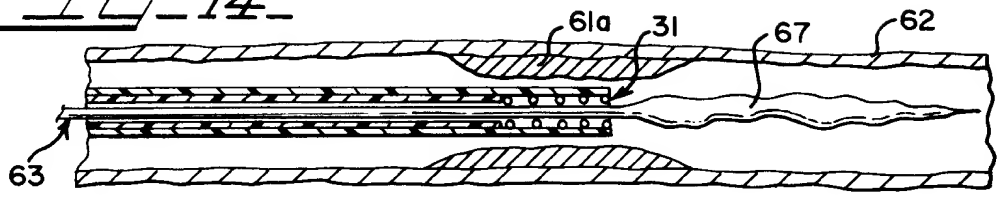


FIG. 15

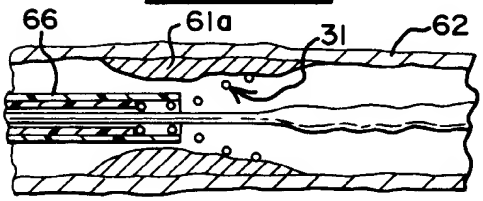


FIG. 16

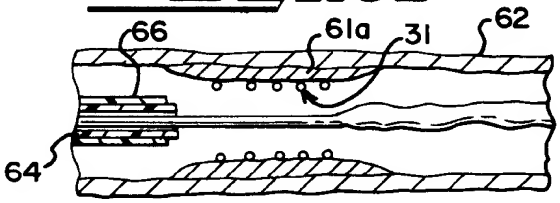


FIG. 17

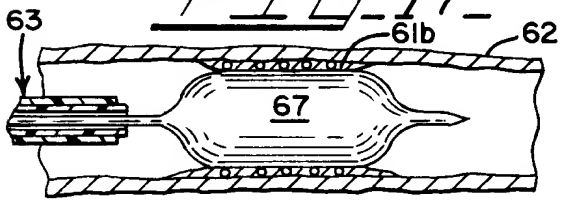


FIG. 18

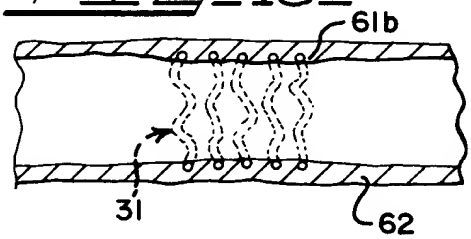


FIG. 24

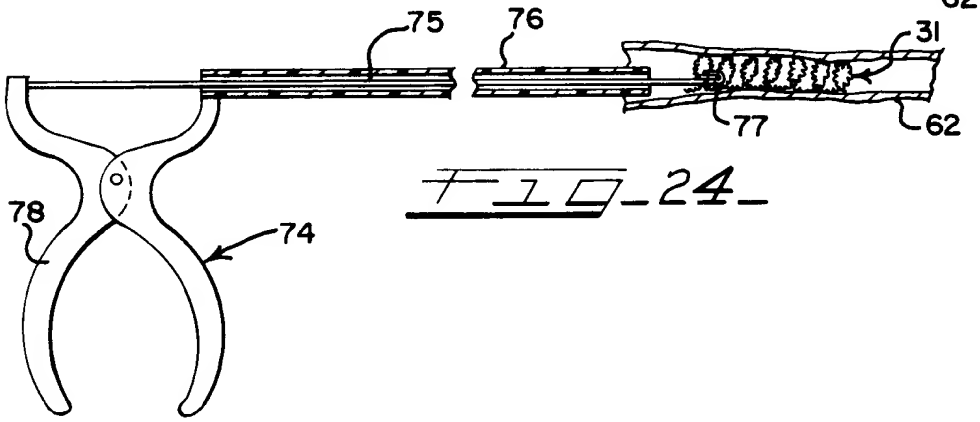
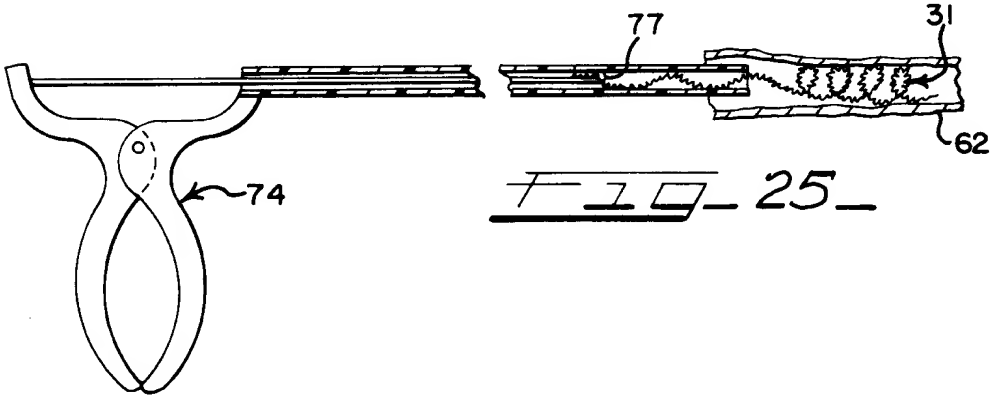


FIG. 25



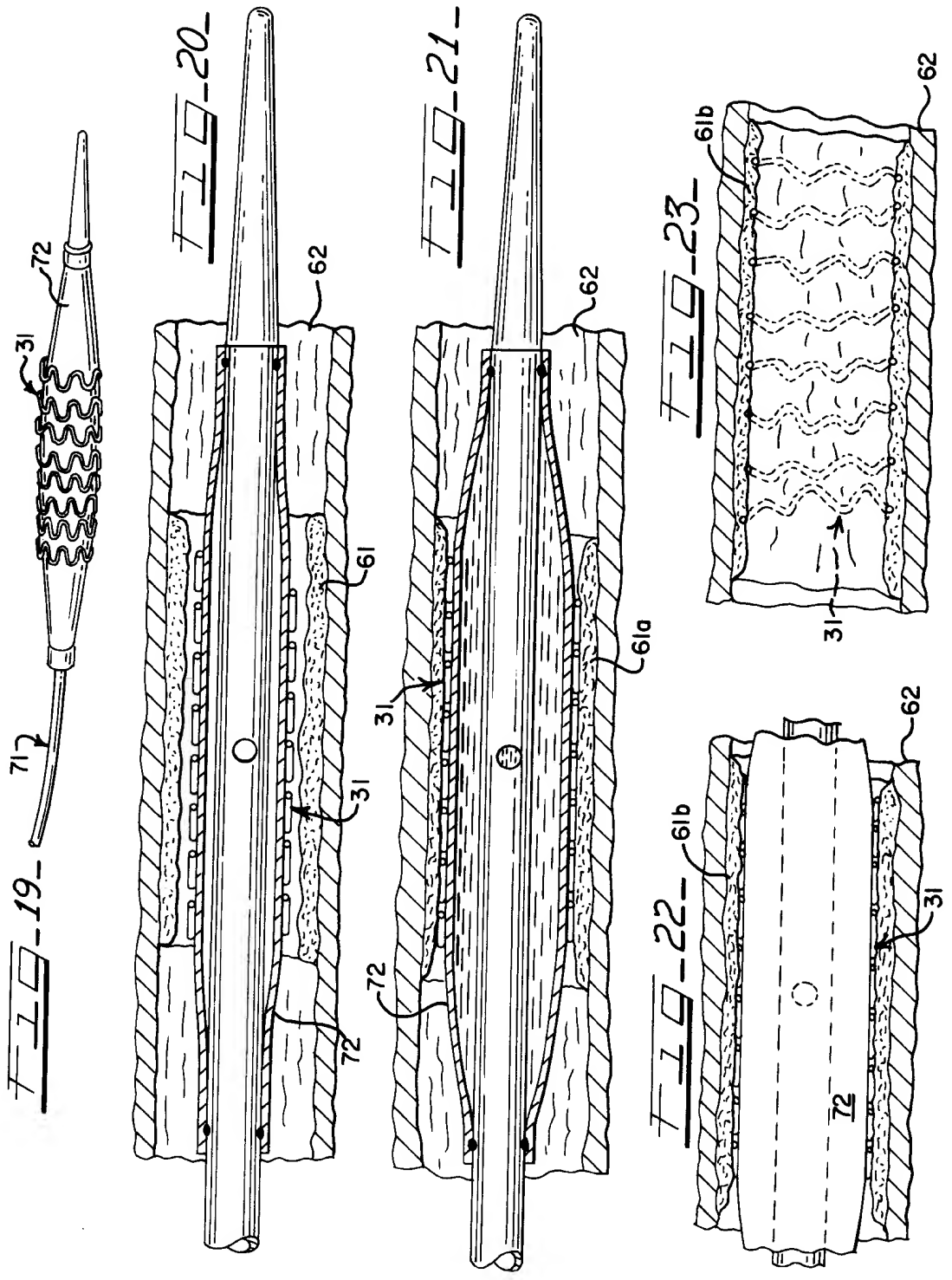


FIG-19

FIG-20

FIG-21

FIG-23

FIG-22

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(54) Radially expandable endoprothesis

Radial ausdehnbare Endoprothese

Endoprothèse expansible radialement

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EP 0 357 003 B2

Description

Background and Description of the Invention

The present invention generally relates to endoprosthesis devices, in particular to a radially expandable endoprosthesis to a procedure for making same, and to a system comprising such an endoprosthesis. More particularly, the invention relates to a radially expandable endoprosthesis according to the preamble of Claim 1. Such an endoprosthesis is known e.g. from US-A-4 580 568. Such a generally tubular endoprosthesis is radially expandable between a generally unexpanded insertion circumference and an expanded implantation circumference which is greater than the unexpanded insertion circumference. Included are a plurality of generally circumferential sections, one or more of which includes one or more expandable segments that are bendable members which are generally collapsed when the endoprosthesis is in its generally unexpanded insertion orientation and which are generally opened when the endoprosthesis is in its expanded implantation orientation.

Endoprostheses are known for treating stenoses, aneurysm conditions and the like. An endoprosthesis device of this type, which is at times referred to as a stent, is typically placed or implanted by a mechanical transluminal procedure. Often a device of this type is percutaneously implanted within the vascular system to reinforce collapsing, partially occluded, weakened or abnormally dilated localized sections of a blood vessel or the like. When endoprostheses or stents are used to treat a stenosis condition, typically such is done in association with a dilation element such as an angioplasty balloon. In this instance, the dilation element or balloon device opens the constriction, and a stent or the like is positioned thereat in order to prevent or at least substantially slow re-formation of the stenosis.

One attribute of a stent is that it is radially compressible and expandable so that it will easily pass through a blood vessel or the like when collapsed and will expand to its implanted size after the stenosis, aneurysm or the like has been reached. It is also desirable that a stent be generally flexible throughout its length so that it is easily maneuverable through bends and curves of the blood vessel or the like. It is typically desirable that a stent or endoprosthesis have a substantial amount of open space so as to allow for endothelialization along its length and to minimize interference with collateral blood vessels and the like. While it is important that a stent or endoprosthesis lodge securely into place at the desired location, it can be advantageous to have a stent that is removable through a transluminal percutaneous procedure, should removal be needed.

Various currently known stent products have structures that are essentially coiled springs. When this type of spring stent is tightly coiled, its diameter is relatively small for insertion through a blood vessel or the like. When the coil is sprung or coiled more loosely, the stent assumes its expanded, implantation orientation. Maass et al U.S. Patent No. 4,553,545 is illustrative of this type of coiled spring stent or endoprosthesis. Multihelix or braided stents are also known, and they suffer from poor maneuverability. They are also difficult to remove once implanted, and they may exhibit numerous exposed, relatively sharp or jagged ends. Palmaz U.S. Patent No. 4,733,665 is representative of an expandable stent of this general type. Gianturco U.S. Patent No. 4,580,568 illustrates a percutaneous endovascular stent formed of stainless steel wire that is arranged in a closed zig-zag pattern somewhat in the nature of a bookbinder spring. Such a structure is somewhat unsymmetrical, and it may be subject to reocclusion due to the very large open space that is typically present between the wires of this type of device. Another type of stent is known as a Statz stent, and it includes a hypodermic tube with longitudinal slots etched into its body. While such a device has a high ratio of unexpanded to expanded diameter, it is a comparatively rigid device which is difficult to maneuver through a tortuous path and is not easily removed in a transluminal manner.

With many of these currently known stent structures, the axial length of the stent decreases as the circumference of the stent increases, which is typically a disadvantage. For example, any such length reduction must be taken into consideration in selecting proper stent sizing for a particular implantation procedure. Also, this attribute of many prior stents requires the passage through the blood vessel or the like of a stent which is longer than the length actually needed for the implantation procedure being performed. This is a particularly difficult problem for procedures in which the stent must be passed through a pathway having twists or turns, especially for a stent structure that is not easily bendable.

EP-A-0 282 175, published on September 14, 1988 i.e. after the priority date of the present application discloses a stent comprising a wire formed into a serpentine configuration including a series of straight sections and a plurality of bends. The free ends of said stent are not engaged with adjacent ones.

US-A-4,580,568 discloses a stent comprising a wire formed into a closed zig-zag configuration including an endless series of straigth sections, a plurality of bends, wherein said straigth sections are joined by said bends to form the stent. In Fig. 7 and 8 of US-A-4,580,568 no free ends of the stent are shown.

US-A-4,665,918 discloses a prosthesis for insertion in a cavity of a human body comprising a cylinder of resilient expandible material in the form of a helical coil of an elastomeric material.

EP-A-0 212 852, published on April 28, 1989 i.e. after the priority date of this application, discloses a radially expandible vesicular stent of the type formed of wire wound generally in a helix, characterized by bends in the wire outside this helical path, which straightens as

the stent is expanded. The stent has free ends which are curled into tight loops and do not engage any adjacent free end.

The present invention avoids the various deficiencies of these types of prior art structures and provides important and advantageous features of endoprostheses or stents.

A subject-matter of the present invention is a radially expandible endoprosthesis as defined in claim 1. Preferred embodiments thereof are subject-matter of claims 2 to 8. Another subject-matter of the present invention is a method for making a radially expandible endoprosthesis as defined in claim 9. Preferred embodiments thereof are subject-matter of claims 10 to 14. Another subject-matter of the present invention is an implantable and explantable endoprosthesis system as defined in claim 15. Preferred embodiments thereof are subject-matter of claims 16-19.

It is a general object of the present invention to provide an improved radially expandable, axially extending endoprosthesis of the type that can be transluminally implanted.

Another object of the present invention is to provide an improved endoprosthesis or stent that can be constructed to have very large radial expansion capabilities.

Another object of this invention is to provide an improved radially expandable axially extending endoprosthesis that is extremely maneuverable and capable of moving through a tortuous path.

Another object of the present invention is to provide an improved radially expandable axially extending endoprosthesis that can, if desired, be transluminally explanted by means of, for example, a snare lead or catheter.

Another object of the present invention is to provide an improved radially expandable axially extending endoprosthesis which includes members that can be spaced apart in a manner that enhances lodging of the endoprosthesis at its implanted site.

Another object of the present invention is to provide an improved axially extending endoprosthesis that can be constructed in order to be radially expandable by an expanding member or balloon of a catheter device and/or can be radially expandable due to spring-like properties of the endoprosthesis.

Another object of this invention is to provide an improved procedure for making an axially extending and/or generally tubular endoprosthesis that is radially expandable.

Another object of the present invention is to provide an improved system comprising an axially extending radially expandable endoprosthesis or stent and a device for transluminally explanting said endoprosthesis.

Another object of the present invention is to provide an improved radially expandable endoprosthesis that substantially avoids the presentation of any frayed edges and that generally maintains its axial length throughout various radial expansion positions.

These and other objects, features and advantages of this invention will be clearly understood through a consideration of the following detailed description.

Brief Description of the Drawings

In the course of this description, reference will be made to the attached drawings, wherein:

Figure 1 is a perspective view illustrating an early step in the procedure of making an endoprosthesis according to the present invention;

Figure 2 is an elevational view illustrating a step subsequent to that shown in Figure 1;

Figure 3 is an elevational view showing a manufacturing step subsequent to that of Figure 2, while also illustrating a substantially completed endoprosthesis in accordance with the present invention;

Figure 4 is a cross-sectional view along the line 4-4 of Figure 3;

Figure 5 is an enlarged detail view of a portion of one end of the endoprosthesis shown in Figure 3;

Figure 6 is a perspective view illustrating an early step in the procedure of making another embodiment of the endoprosthesis;

Figure 7 is an elevational view illustrating a step subsequent to that shown in Figure 6, while also illustrating the configuration of a portion of this endoprosthesis prior to its circumferential orientation;

Figure 8 is a perspective view illustrating an early step in the procedure of making a further embodiment of the endoprosthesis;

Figure 9 is an elevational view illustrating a step subsequent to that shown in Figure 8, while also illustrating the configuration of a portion of this endoprosthesis prior to its circumferential orientation;

Figure 10 is an elevational view of an early step in the manufacturing procedure for still a further embodiment of the endoprosthesis;

Figure 11 is an elevational view of a step subsequent to that shown in Figure 10;

Figure 12 is an elevational view of a manufacturing step subsequent to that illustrated in Figure 11 and which shows a length of material suitable for winding on a mandrel in a generally helical manner in order to form the endoprosthesis of this embodiment;

Figure 13 is a generally cross-sectional view illustrating an early step in a procedure for implanting an endoprosthesis according to the present invention, this particular procedure being especially suitable for an endoprosthesis having spring-like properties;

Figure 14 is a generally cross-sectional view illus-

trating an implantation step subsequent to that shown in Figure 13;

Figure 15 is a generally cross-sectional view illustrating an implantation step subsequent to that of Figure 14;

Figure 16 is a generally cross-sectional view illustrating an implantation step subsequent to that illustrated in Figure 15;

Figure 17 is a generally cross-sectional view of an implantation step subsequent to that illustrated in Figure 16;

Figure 18 is a generally cross-sectional view of an implanted stent or endoprosthesis in accordance with the present invention;

Figure 19 is an elevational view of an endoprosthesis and distal end of a balloon catheter for an implantation procedure that is especially suitable for an endoprosthesis according to the present invention that is constructed of a malleable-type of material;

Figure 20 is a generally cross-sectional illustration of the endoprosthesis and catheter of Figure 19 positioned within a blood vessel;

Figure 21 is a generally cross-sectional illustration of an implantation stage subsequent to that shown in Figure 20;

Figure 22 is a generally cross-sectional illustration of an implantation stage subsequent to that shown in Figure 21;

Figure 23 is a generally cross-sectional illustration of an implanted stent or endoprosthesis according to the present invention;

Figure 24 is a generally cross-sectional illustration of a snare catheter shown explanting a stent or endoprosthesis in accordance with the present invention; and

Figure 25 is a generally cross-sectional illustration showing a further stage of the explantation procedure illustrated in Figure 24.

Description of the Particular Embodiments

A radially expandable axially extending endoprosthesis or stent is generally designated as 31 in Figure 3, as well as in Figure 4. The stent includes a plurality of generally circumferential sections 32. In this illustrated embodiment, each of the circumferential sections 32 are formed from the same continuous, helically wrapped length, such as the undulating length 33 shown in Figure 2.

At least one of the circumferential sections 32 includes at least one expandable segment 34. Expandable segment 34 is a bendable member that typically includes one or more legs 35. Each leg 35 is bendably secured to the rest of the circumferential section 32 by a so-called living joint or hinge that is a unitary or integral component of the leg 35 and the adjacent portion of the circumferential section 32. For example, in the embodiment illustrated in Figures 1 through 5, each leg 35 is bendably joined to another leg 35 through an integral or living hinge 36 which has a generally arcuate shape. When the stent 31 expands, the integral hinge 36 permits end portions 37 of the legs 35 to move farther apart, thereby increasing the circumference and diameter of the stent 31. Of course, the circumference and diameter of the stent 31 can be reduced by forces which move these end portions 37 closer to each other.

An understanding of the manner in which the endoprostheses according to this invention, such as the stent 31, can be made will be obtained from a consideration of Figures 1, 2 and 3. Figure 1 shows a mandrel 38 that has a cross-sectional configuration that is somewhat oval in shape. Mandrel 38 can, for example, be a circular tube that has been flattened on two opposing longitudinal portions in order to provide a cross-section that is generally rectangular in shape, with two opposing end portions thereof being arcuate or rounded. A strand 39 of wire or other material, as generally discussed elsewhere herein, is generally tightly wound over the mandrel to the extent that the strand 39 takes on a cross-sectional shape along the lines of that of the mandrel 38. Preferably, this winding is done in a manner such that there is a substantial spacing between each individual wind of the strand 39. Generally speaking, the tighter the wind and the thinner the mandrel, the closer will be the spacing between the expandable segments 34 of the completed stent 31.

After this winding procedure has been completed, the mandrel 38 is removed from the wound strand 39. The wound strand 39 is then subjected to flattening forces so that the three-dimensional wound strand 39 is transformed into a generally planar shape such as that of the undulating length 33 shown in Figure 2. These forces may be applied by any suitable means. For example, the wound strand 39 can be compressed between two planar surfaces, during which procedure, portions of the wound strand 39 are twisted until the generally uni-planar undulating length 33 is formed. This length has a generally sinusoidal character.

In order to complete formation of the stent 31 illustrated in Figure 3, the undulating length 33 is then wound, in a generally helical manner, around a substantially cylindrical mandrel 41, as is generally illustrated in Figure 3. This generally helical wrapping procedure continues until the desired number of circumferential sections are formed in order to provide a stent 31 of a desired length.

With reference to Figure 5, this winding procedure that is generally illustrated in Figure 3 includes proceeding in a manner so as to avoid the presentation of any loose ends in the completed stent 31. This is readily accomplished by forming the strand 39 and the undulating length 33 so that each end circumferential section 42 has a free end 43 that readily hooks onto an adjacent portion of the stent 31, such as an integral hinge 36 of the circumferential section 32 that is adjacent to and

inwardly spaced from the end circumferential section 42. The free end 43 illustrated in Figure 5 is in the nature of a hook portion that readily loops or tucks into the integral hinge 36.

Regarding the embodiment shown in Figures 6 and 7, the mandrel around which the strand 39 is wound is a substantially rectangular mandrel 44. As a result, the generally planar structure that is subsequently formed is an undulating length 45 that includes a plurality of legs 46 joined by a unitary or integral hinge or living hinge 47 that is typically less arcuate than the integral hinge 36. This undulating length 45 is then formed into an endoprosthesis or stent by helically winding same on a structure such as the cylindrical mandrel 41.

Another embodiment of the endoprosthesis or stent is made in a manner generally illustrated in Figures 8 and 9. Here, the mandrel is a generally lens-shaped mandrel 51 which has a transverse cross-section that can be described as defining two convex surfaces positioned in back-to-back relationship with each other. Much in the same manner as the other embodiments, the elongated strand 39 is wound around the lens-shaped mandrel 51. The mandrel 51 is subsequently moved therefrom, and the wound strand 39 is rendered substantially uniplanar in order to form undulating length 52 that is suitable for forming into a stent by wrapping around the mandrel 41.

Another embodiment illustrating the manufacture of an endoprosthesis or stent in accordance with this invention is generally illustrated in Figures 10, 11 and 12. A strand is wound around a small-diameter mandrel 53. In this case, the strand is formed into a tightly wound helix 54. Thereafter, the mandrel 53 is removed, and the strand is formed into a more loosely wound helix 55. For example, the helix 55 can be elongated such that the pitch angle is less than approximately 60°. This helix 55 is then flattened generally in the manner previously discussed, for example to 15.000 kg (15 tons) in a pneumatic press, in order to form a generally uni-planar undulating length 56. If desired, the length 56 can be axially compressed in a contained mold to the desired pitch angle. Length 56 is suitable for winding around cylindrical mandrel 41 in order to thereby form an endoprosthesis or stent.

Stents illustrated herein are typically capable of moving through a tortuous path that may be encountered in vascular system implantation. Such stents can be easily axially bent over a relatively small radius without damage or high bending resistance.

It should be appreciated that in the illustrated embodiments, each circumferential section 32 is generally identical. It is also possible within the spirit of the invention to provide circumferential sections that are not this uniformly shaped. For example, the circumference of adjacent sections can differ in order to form a stent that is not strictly shaped in the nature of a right cylinder. For example, tapered, truncated cone-shaped stents or stepped stents can be provided. In addition, in some applications, it can be suitable to include circumferential sections that are not composed entirely of expandable segments, but instead could include non-expandable portions that are joined by expandable segments. It also may be possible to provide stents within the spirit of the present invention which include one or more circumferential sections that form a stent device without proceeding with helical winding around cylindrical mandrel 41 or the like. It is also possible to provide a stent that has a generally bifurcated structure for use in situations in which the stenosis, aneurysm or the like that is to be treated is at a branching location within the vascular system or the like. Such a bifurcated stent structure can be formed, for example, by joining portions of the opposing ends of two different unitary stents in order to provide a total structure that is bifurcated, Y-shaped or the like.

The materials out of which stents according to the present invention can be made, and especially the expandable segments thereof, fall into two general categories. The material can be either elastic or generally inelastic. Examples of elastic materials include spring steels, stainless steel, Nitinol®, Elgiloy®, an alloy known as NP36N, and the like. Generally inelastic materials can be characterized as being malleable. Included are tantalum, titanium, silver, gold, and annealed versions of the elastic materials described herein. Polymers may also be used, such as polyether sulfone, polyimide, polycarbonate, polypropylene, ultra high molecular weight polyethylene, carbon fiber, Kevlar®, and the like. It is also possible to coat these materials with porous or textured surfaces for cellular ingrowth and the like or with non-thrombogenic agents such as pyrolytic carbon, heparin, hydrogels, Teflon materials, silicones, polyurethanes and the like. The stents can be treated so that drugs can be eluted therefrom. It is also possible that certain stents may be made of biodegradable materials. In any event, the stent material, of course, is to be biocompatible.

Figures 13 through 18 illustrate an implantation procedure and an insertion system that is particularly suitable for stents that are constructed of an elastic material such as spring steel. A stenosis or lesion 61 is shown within a blood vessel 62. The stent 31 is positioned on a balloon catheter, generally designated as 63. An introducer tube or plunger 64, or a similar stop-providing structure, is positioned along the outside surface of the catheter tube 65. The stent 31 is located distally of the member 64, and a sheath 66 holds the stent 31 in a generally compressed state during which the expandable segments of the stent 31 are generally collapsed or closed. Figure 13 further shows the balloon 67 of the catheter in a mode in which it is exerting outwardly radially directed forces on the lesions in order to dilate same to provide a wider opening as generally illustrated in Figure 14 in order to thereby generally reduce the overall extent of the lesion 61a. At this time, the balloon 67 is collapsed, and the catheter 63 is moved in a distal

direction so that the collapsed stent 31 is generally positioned within the lesion 61a. Next, as illustrated in Figure 15, the sheath 66 is withdrawn by moving same in a generally proximal direction, and the stent 31 is released from the sheath 66. This release can be such that adjacent circumferential sections of the stent expand in a generally sequential manner, which is generally illustrated in Figure 15.

After this procedure is completed, the entire stent 31 has been sprung, and it springingly engages the dilated lesion 61a, which is generally illustrated in Figure 16. Thereafter, as seen in Figure 17, the catheter 63 can be moved in a generally proximal direction until the balloon 67 is again generally aligned with the dilated lesion 61a, as desired. Then, the balloon 67 can be pressurized in order to further implant the stent 31 and in order to further dilate the lesion as desired so as to form a treated lesion 61b which remains after the catheter 63 is removed, as is generally shown in Figure 18.

Figures 19 through 23 show an arrangement that is especially suitable for non-elastic stents in which the expandable segments thereof are made of malleable material. With reference to Figures 19 and 20, a stenosis or lesion 61 within blood vessel 62 is transluminally reached by a balloon catheter 71 having a stent 31 overlying the collapsed balloon 72 of the catheter 71. The balloon 72 is then expanded in a well-known manner, at which time the stent 31 is also expanded by opening the expandable segments thereof. An intermediate dilation position is shown in Figure 21, and an initially dilated lesion 61a is shown therein. Figure 22 shows additional dilation by the balloon 72, and the thus treated lesion 61b is also shown. After this stage is achieved, the balloon catheter 71 is removed, as shown in Figure 23.

The stent 31 remains in place as generally illustrated in Figure 23 because the malleable material (or for that matter an elastic material) exerts a hoop stress when it is expanded to the size illustrated in Figure 23 such that it will not collapse by inwardly directed radial forces presented by the treated lesion and vessel wall or the like. In other words, the hoop stress of the expanded stent is greater than the hoop forces exerted by the passageway within which the stent is implanted. In addition, the force required to open the collapsed stent by the balloon is less than the hoop force provided by. the balloon. In other words, the hoop stress of the collapsed or unextended stent is less than that of the hoop force provided by the pressurized balloon of the catheter. One feature that can contribute to the advantageous hoop stress properties of the malleable stents of the type illustrated in the drawings is the ability of the stent to expand well beyond that needed to effect the dilation procedure. For example, a typical dilation procedure and stent extension is one in which the fully extended dilating diameter or circumference is approximately three times the insertion or collapsed diameter or circumference. With stent structures such as those illustrated in the drawings, the amount of possible expansion can be on the order of twelve times. This feature, together with the malleability of the particular material utilized, tends to reduce the hoop force that is needed to expand the stent to about three times its insertion or collapsed configuration.

Figures 24 and 25 illustrate a stent withdrawal procedure and a snare catheter system that can be used to remove or explant implanted stents according to the present invention. A snare catheter, generally designated as 74, is illustrated. An elongated member 75 is slidably positioned within a catheter body 76. Elongated member 75 includes a hook member 77 at its distal end. When extended into the stent 31, the hook member 77 snares a portion of the stent 31. A suitable control structure, such as the puller assembly 78 illustrated is manipulated in order that the hook member moves in a proximal direction, with the result that the stent begins to uncoil and is opened to such an extent that it can be passed through the blood vessel 62 or the like until it is totally removed from the body by continued movement of the elongated member 75 in the proximal direction.

For purposes of illustration, the following details are given regarding a typical stent 31. An exemplary malleable material is tantalum wire having a diameter of 0.013 cm (0.005 inch) wound on a mandrel having a nominal diameter of 0.051 cm (0.020 inch). The length of each leg 46 is on the order of about 0.122 cm (0.048 inch), and the center-to-center spacing between adjacent integral or living hinges 36 is about 0.107 cm (0.042 inch). A typical collapsed or insertion outer diameter for such a stent is about 0.216 cm (0.085 inch), with the inner diameter thereof being about 0.178 cm (0.070 inch). The overall length of the stent 31 is selected to be that generally needed to treat the lesion or the like inasmuch as the overall length of the stent will remain substantially the same whether it is collapsed or extended, except to the degree that the legs 46 of the exterior circumferential sections 32 move somewhat inwardly as the hinge is flexed, thereby somewhat nominally decreasing the overall length of the stent.

Claims

1. A radially expandable endoprosthesis, comprising:

   a plurality of generally circumferential sections (32), said generally circumferential sections being substantially adjacent to one another and generally axially oriented with respect to each other in order to thereby generally define an endoprosthesis (31); at least one of said generally circumferential sections includes an expandable segment (34) that imparts radial expandability to said generally circumferential section whereby said section has an unexpanded insertion circumference and an expanded implantation circumference which is greater than said unexpanded insertion circumference; and said expandable segment of the

generally circumferential section is a generally foldable member that is bendable between a generally closed orientation and a generally openend orientation so as to impart radial expandability to the generally circumferential section (32), characterized in that each outside one of said generally circumferential sec-tions has a free end (43) engaged with an adjacent one of said generally circumferential sections, and each said thus engaged free end avoids the presentation of any loose ends in the completed endoprosthesis.

2. The endoprosthesis according to claim 1, wherein said foldable member includes a generally elbow-like member that is a living hinge (36) unitary connecting a pair of legs (35), and said generally circumferential sections form a substantially cylindrical endoprosthesis.

3. The endoprosthesis according to claim 1 or 2, wherein said free end (43) has hook means (43) for engaging an adjacent one of said generally circumferential sections (32).

4. The endoprosthesis according to claim 1, 2 or 3 wherein said expandable segment is a generally foldable elastic spring-like member, and wherein the unexpanded insertion circumference of the endoprosthesis is maintained by an overlying sheath (66).

5. The endoprosthesis according to claim 1, 2 or 3, wherein said expandable segment is a generally foldable malleable member, and wherein the expanded implantation circumference is achieved by radially directed forces from an expandable element (72) of a catheter (71).

6. The endoprosthesis according to any of claims 1-5, wherein said generally foldable member (52, 56) is substantially V-shaped.

7. The endoprosthesis according to any of claims 1-6, wherein said endoprosthesis is generally tubular, and respective circumferential edges of respective generally circumferential sections are generally adjacent to each other.

8. The endoprosthesis according to any of claims 1-7, wherein said expandable segment of the generally circumferential section had been formed by a process including winding a strand (39) on a shaped mandrel (38, 44, 51, 53) to form a wound strand which was subsequently flattened to a generally uni-planar configuration (33, 45, 52, 56).

9. A method for making a radially expandable endoprosthesis, comprising:

selecting a mandrel (38, 44, 51, 53) having a relatively small cross-sectional area in order to provide a narrow wrapping surface;
winding an elongated strand (39) around said narrow wrapping surface and removing the strand from said small mandrel so as to form a wound strand having a plurality of turns therein, said turns being shaped to generally conform to the shape of said cross-sectional area;
subjecting said wound strand to flattening forces in order to form a generally uni-planar undulating strand length (33, 45, 52, 56);
providing another mandrel (41) having a cross-sectional area greater than that of said relatively small mandrel;
generally helically wrapping said undulating strand length around said another mandrel and removing said another mandrel to thereby provide a radially expandable endoprosthesis (31); and
engaging a free end (43) of said undulating strand length with an adjacent portion of said undulating strand length after said generally helically wrapping step has been initiated, thereby avoiding the presentation of loose ends on the endoprosthesis.

10. The method according to claim 9 , wherein said providing step includes selecting the another mandrel to have a generally cylindrical outer surface.

11. The method according to claim 9 or 10 , wherein said selecting step includes choosing the relatively small mandrel (38) so that the wrapping surface is generally oval in shape.

12. The method according to claim 9 or 10 , wherein said selecting step includes choosing the relatively small mandrel (44) so that the wrapping surface is generally rectangular in shape.

13. The method according to claim 9 or 10 , wherein said selecting step includes choosing the relatively small mandrel (51) so that the wrapping surface is generally lens-shaped in shape.

14. The method according to claim 9 or 10 , wherein said selecting step includes choosing the relatively small mandrel (53) so that the wrapping surface is generally circular in shape.

15. An implantable and explantable endoprosthesis system, comprising a radially expandable axially extending endoprosthesis (31) and a device (74) for transluminally explanting the endoprosthesis; said endoprosthesis includes:

a plurality of generally circumferential sections (32), said generally circumferential sections being substantially adjacent to one another and generally axially oriented with respect to each other in order to thereby generally define an endoprosthesis,

at least one of said generally circumferential sections includes an expandable segment (34) that imparts radial expandability to said generally circumferential section whereby said section has an unexpanded insertion circumference and an expanded implantation circumference which is greater than said unexpanded insertion circumference, and

said expandable segment of the generally circumferential section is a generally foldable member that is bendable between a generally closed orientation and a generally opened orientation so as to impart radial expandability to the generally circumferential section (32); characterized in that an outside one of said generally circumferential sections has a free end (43) engaged with an adjacent one of said generally circumferential sections; and

in that said device for transluminally explanting the endoprosthesis includes:

an elongated member (75) that is percutaneously insertable into a blood vessel (62) or the like within which said endoprosthesis has been radially expanded and implanted, said elongated member having a proximal portion exterior of the body,

snaring means (77) at a distal end of the elongated member,

means for manipulating a proximal portion of the elongated member from a location exterior of the body, said manipulating means facilitating engagement of said snaring means with one of said circumferential sections of the implanted endoprosthesis,

puller means (78) for sliding the elongated member in a proximal direction by moving the body-exterior proximal portion of the elongated member in a direction away from the endoprosthesis,

said puller means further being for reducing the radial size of the endoprosthesis to less than said expanded implantation circumference and such that it will pass through the blood vessel or the like, and

means for completely removing the elongated member from the body until the endoprosthesis of reduced radial size has been fully explanted.

16. The system according to claim 15 , wherein said generally circumferential sections form a continuous helix that defines the axially extending endoprosthesis, and wherein said puller means is for at least partially uncoiling said helix.

17. The system according to claim 15 , wherein said puller means is for uncoiling the endoprosthesis being explanted.

18. The system according to claim 15, 16 or 17, further including a catheter body (76) within which said elongated member is slidably mounted.

19. The system according to claim 15, 16, 17 or 18, wherein said snaring means includes a hook member.

Patentansprüche

1. Radial ausdehnbare Endoprothese, umfassend: eine Mehrzahl von im allgemeinen umfangsmäßigen Bereichen (32), wobei die im allgemeinen umfangsmäßigen Bereiche im wesentlichen einander benachbart sind und in Bezug zueinander im allgemeinen axial ausgerichtet sind, um dadurch im allgemeinen eine Endoprothese zu definieren (31);

wobei mindestens einer der im allgemeinen umfangsmäßigen Bereiche ein ausdehnbares Segment (34) umfaßt, welches dem im allgemeinen umfangsmäßigen Bereich eine radiale Ausdehnbarkeit verleiht, wobei der Bereich einen nicht ausgedehnten Insertionsumfang und einen ausgedehnten Implantationsumfang, der größer als der nicht ausgedehnte Insertionsumfang ist, hat, und worin

das ausdehnbare Segment des im allgemeinen umfangsmäßigen Bereichs ein im allgemeinen faltbares Bauelement ist, das biegbar zwischen einer im allgemeinen geschlossenen Ausrichtung und einer im allgemeinen geöffneten Ausrichtung ist, um dem im allgemeinen umfangsmäßigen Bereich (32) eine radiale Ausdehnbarkeit zu verleihen, dadurch gekennzeichnet, daß jede Außenseite der umfangsmäßigen Bereiche ein freies Ende (43) hat, das im Eingriff mit einem der benachbarten, im allgemeinen umfangsmäßigen Bereiche ist, und worin jedes derart im Eingriff befindliche Ende das Vorliegen von losen Enden in der vollständigen Endoprothese vermeidet.

2. Endoprothese nach Anspruch 1, worin das faltbare Element ein im allgemeinen ellbogenartiges Element umfaßt, das eine lebende Verbindung (36) ist, die ein Paar von Schenkeln (35) zu einer Einheit verbindet und worin die im allgemeinen umfangsmäßigen Bereiche eine im wesentlichen zylindrische Endoprothese bilden.

3. Endoprothese nach Anspruch 1 oder 2, worin das

freie Ende (43) Hakenmittel (43) zum Eingreifen in einen der benachbarten im allgemeinen umfangsmäßigen Bereiche (32) aufweist.

4. Endoprothese nach Anspruch 1, 2 oder 3, worin das ausdehnbare Segment ein im allgemeinen faltbares elastisches federartiges Element ist und worin der nicht ausgedehnte Binführungsumfang der Endoprothese durch eine darüberliegende Hülle (66) aufrechterhalten wird.

5. Endoprothese nach Anspruch 1, 2 oder 3, worin das ausdehnbare Segment ein im allgemeinen faltbares, verformbares Element ist und worin der ausgedehnte Implantationsumfang durch radial gerichtete Kräfte von einem expandierbaren Element (72) eines Katheters (71) erreicht wird.

6. Endoprothese nach einem der Ansprüche 1 bis 5, worin das im allgemeinen faltbare Element (52,56) im wesentlichen V-förmig ist.

7. Endoprothese nach einem der Ansprüche 1 bis 6, worin die Endoprothese im allgemeinen rohrförmig ist und entsprechende umfangsmäßige Ränder entsprechender im allgemeinen umfangsmäßiger Bereiche im allgemeinen einander benachbart sind.

8. Endoprothese nach einem der Ansprüche 1 bis 7, worin das ausdehnbare Segment des im allgemeinen umfangsmäßigen Bereichs durch ein Verfahren gebildet wurde, welches das Wickeln eines Strangs (39) auf einen geformten Dorn (38,44,51,53) umfaßt, um einen gewundenen Strang zu bilden, der nachfolgend zu einer im allgemeinen uniplanaren Konfiguration (33,45,52,56) abgeflacht wurde.

9. Verfahren zum Herstellen einer radial ausdehnbaren Endoprothese, umfassend:

Auswählen eines Dorns (38, 44, 51, 53) mit einem relativ kleinen Querschnitt, um eine enge Umhüllungsoberfläche vorzusehen,
Wickeln eines langgestreckten Strangs (39) um die enge Umhüllungsoberfläche und Entfernen des Strangs von dem kleinen Dorn, um einen gewundenen Strang mit einer Vielzahl von Windungen darin zu bilden, wobei die Windungen derart geformt sind, daß sie im allgemeinen mit der Form des Querschnitts übereinstimmen,
Unterwerfen des gewundenen Strangs unter Abflachungskräfte, um ein im allgemeinen uniplanares, wellenförmiges Strangstück (33,45,52,56) zu bilden,
Bereitstellen eines weiteren Dorns (41) mit einem Querschnitt, der größer als derjenige des relativ kleinen Dorns ist,
im allgemeinen helicales Wickeln des wellenförmigen Strangstücks, um den weiteren Dorn und Entfernen des weiteren Dorns, um dadurch eine radial ausdehnbare Endoprothese (31) bereitzustellen und
in Eingriff bringen eines freien Endes (43) des wellenförmigen Strangstücks mit einem benachbarten Teil des wellenförmigen Strangstücks nachdem der im allgemeinen helicale Einwickelschritt begonnen wurde, wodurch das Vorliegen von losen Enden an der Endoprothese vermieden wird.

10. Verfahren nach Anspruch 9, worin der Bereitstellungsschritt umfaßt, daß der weitere Dorn eine im allgemeinen zylindrische, Außenfläche aufweist.

11. Verfahren nach Anspruch 9 oder 10, worin der Auswahlschritt ein Auswählen des relativ kleinen Dorns (38) umfaßt,sodaß die Umwicklungsoberfläche eine im allgemeinen ovale Form aufweist.

12. Verfahren nach Anspruch 9 oder 10, worin der Auswahlschritt ein Auswählen des relativ kleinen Dorns (44) umfaßt, sodaß die Umwicklungsoberfläche eine im allgemeinen rechteckige Form aufweist.

13. Verfahren nach Anspruch 9 oder 10, worin der Auswahlschritt ein Auswählen des relativ kleinen Dorns (51) umfaßt, sodaß die Umwicklungsoberfläche eine im allgemeinen linsenförmige Form aufweist.

14. Verfahren nach Anspruch 9 oder 10, worin der Auswahlschritt ein Auswählen des relativ kleinen Dorns (53) umfaßt,sodaß die Umwicklungsoberfläche eine im allgemeinen runde Form aufweist.

15. Implantierbares und explantierbares Endoprothesesystem, umfassend eine radial ausdehnbare, sich axial erstreckende Endoprothese (31) und eine Vorrichtung (74) zum transluminalen Explantieren der Endoprothese, wobei die Endoprothese umfaßt:

eine Mehrzahl von im allgemeinen umfangsmäßigen Bereichen (32), wobei die im allgemeinen umfangsmäßigen Bereiche im wesentlichen einander benachbart sind und in Bezug zueinander im allgemeinen axial ausgerichtet sind, um dadurch im allgemeinen eine Endoprothese zu bilden;

wobei mindestens einer der im allgemeinen umfangsmäßigen Bereiche ein ausdehnbares Segment (34) umfaßt, welches dem im allgemeinen umfangsmäßigen Bereich eine radiale Ausdehnbarkeit verleiht, wobei der Bereich einen nicht ausgedehnten Einfüh-

rungsumfang und einen ausgedehnten Implantationsumfang, der größer als der nicht ausgedehnte Einführungsumfang ist, umfaßt, und worin

das ausdehnbare Segment des im allgemeinen umfangsmäßigen Bereichs ein im allgemeinen faltbares Element ist, das biegbar zwischen einer im allgemeinen geschlossenen Ausrichtung und einer im allgemeinen geöffneten Ausrichtung ist, um dem im allgemeinen umfangsmäßigen Bereich (32) eine radiale Ausdehnbarkeit zu verleihen, dadurch gekennzeichnet, daß ein außenseitiger der im allgemeinen umfangsmäßigen Bereiche ein freies Ende (43) hat, das im Eingriff mit einem benachbarten, der im allgemeinen umfangsmäßigen Bereiche ist, und daß die Vorrichtung zum transluminaren Explantieren der Endoprothese umfaßt:

ein langgestrecktes Element (75), das perkutan in ein Blutgefäß (62) oder dergleichen einschiebbar ist, innerhalb welchem die Endoprothese radial ausgedehnt und implantiert worden ist, wobei das langgestreckte Element einen proximalen Abschnitt außerhalb des Körpers hat,

Schlingenmittel (77) an einem distalen Ende des langgestreckten Elements,

Mittel zum Handhaben eines proximalen Abschnitts des langgestreckten Elements von einem außerhalb des Körpers gelegenen Ort aus, wobei die Handhabungsmittel das Eingreifen der Schlingenmittel in einen der umfangsmäßigen Bereiche der implantierten Endoprothese erleichtern,

Ziehmittel (78) zum gleitenden bewegen des langgestreckten Elements in eine proximale Richtung durch Bewegen des außerhalb des Körpers gelegenen proximalen Abschnitts, des langgestreckten Elements in eine Richtung weg von der Endoprothese,

wobei das Ziehmittel weiterhin zum Verringern der radialen Größe der Endoprothese auf eine kleinere Größe als der ausgedehnte Implantationsumfang und derart, daß sie durch das Blutgefäß oder dergleichen gelangen wird, dienen und

Mittel zum vollständigen Entfernen des langgestreckten Elements aus dem Körper bis die Endoprothese mit verringerter radialer Größe vollständig explantiert ist.

16. System nach Anspruch 15, worin die im allgemeinen umfangsmäßigen Bereiche eine kontinuierliche Helix bilden, welche die sich axial ausdehnende Endoprothese bildet und worin das Ziehmittel dazu dient die Helix zumindest teilweise abzuwickeln.

17. System nach Anspruch 15, worin das Ziehmittel zum Abwickeln der zu explantierenden Endoprothese dient.

18. System nach Anspruch 15, 16 oder 17, weiterhin umfassend einen Katheterkörper (76), innerhalb welchem das langgestreckte Element verschiebbar angebracht ist.

19. System nach Anspruch 15, 16, 17 oder 18, worin das Schlingenmittel ein Hakenelement umfaßt.

Revendications

1. Endoprothèse expansible radialement, comprenant :

une pluralité de sections généralement circonférentielles (32), ces sections généralement circonférentielles étant sensiblement contiguës entre elles et orientées généralement axialement l'une par rapport à l'autre pour définir ainsi de façon générale une endoprothèse (31) ; au moins l'une des sections généralement circonférentielles comprend un segment expansible (34) qui confère une expansibilité radiale à la section généralement circonférentielle, cette section ayant une circonférence d'insertion non expansée et une circonférence d'implantation expansée qui est supérieure à la circonférence d'insertion non expansée ; et le segment expansible de la section généralement circonférentielle est un élément généralement pliable qui est cintrable entre une orientation généralement fermée et une orientation généralement ouverte de façon à impartir une expansibilité radiale à la section généralement circonférentielle (32), caractérisée en ce que chaque section extérieure des sections généralement circonférentielles présente une extrémité libre (43) coopérant avec une section contiguë des sections généralement circonférentielles, et chaque extrémité libre ainsi engagée évite la présentation de toute section détachée dans l'endoprothèse terminée.

2. Endoprothèse selon la revendication 1, dans laquelle l'élément pliable comprend un élément généralement en forme de coude qui est une articulation mobile (36) raccordant unitairement une paire de branches (35) et les sections généralement circonférentielles forment une endoprothèse sensiblement cylindrique.

3. Endoprothèse selon la revendication 1 ou 2, dans laquelle l'extrémité libre (43) présente un moyen de crochet (43) pour coopérer avec une section contiguë des sections généralement circonférentielles

(32).

4. Endoprothèse selon la revendication 1, 2 ou 3, dans laquelle le segment expansible est un élément de type ressort élastique généralement pliable et dans lequel la circonférence d'introduction non expansée de l'endoprothèse est maintenue par une gaine de recouvrement (66).

5. Endoprothèse selon la revendication 1, 2 ou 3, dans laquelle le segment expansible est un élément malléable généralement pliable et dans lequel la circonférence d'implantation expansée est obtenue par des forces dirigées radialement à partir d'un élément expansible (72) d'un cathéter (71).

6. Endoprothèse selon l'une quelconque des revendications 1-5, dans laquelle l'élément généralement pliable (52, 56) est sensiblement en forme de V.

7. Endoprothèse selon l'une quelconque des revendications 1-6, dans laquelle l'endoprothèse est en général tubulaire et les bords circonférentiels respectifs des sections généralement circonférentielles respectives sont généralement contiguës entre elles.

8. Endoprothèse selon l'une quelconque des revendications 1-7, dans laquelle le segment expansible de la section généralement circonférentielle a été formé par un procédé comprenant l'étape d'enroulement d'un fil (39) sur un mandrin formé (38, 44, 51, 53) pour former un fil enroulé qui a été ultérieurement aplati pour donner une configuration généralement uniplanaire (33, 45, 52, 56).

9. Procédé pour la fabrication d'une endoprothèse radialement expansible, comprenant les étapes consistant à :

choisir un mandrin (38, 44, 51, 53) de section transversale relativement petite pour fournir une surface d'enroulement étroite ;
enrouler un fil allongé (39) autour de la surface d'enroulement étroite et enlever le fil du petit mandrin de façon à former un fil enroulé ayant une pluralité de spires, ces spires étant formées de façon à s'adapter généralement à la forme de la section transversale ;
soumettre ce fil enroulé à des forces d'aplatissement pour former un tronçon de fil ondulant de façon générale uniplanaire (33, 45, 52, 56) ;
fournir un autre mandrin (41) ayant une surface transversale supérieure à celle du mandrin relativement petit ;
enrouler de façon générale hélicoïdalement le tronçon de fil ondulant autour d'un autre mandrin en enlever l'autre mandrin pour fournir ainsi une endoprothèse radialement expansible (31) ; et
engager une extrémité libre (43) du tronçon de toron ondulant avec une portion contiguë du tronçon de fil ondulant après avoir commencé l'étape d'enroulement de façon généralement hélicoïdalement, évitant ainsi la présentation d'extrémités détachées sur l'endoprothèse.

10. Procédé selon la revendication 9, dans lequel l'étape consistant à prévoir le mandrin comporte la sélection de l'autre mandrin de surface extérieure généralement cylindrique.

11. Procédé selon la revendication 9 ou 10, dans lequel l'étape de sélection comprend le choix d'un mandrin relativement petit (38) de façon que la surface d'enroulement soit de forme généralement ovale.

12. Procédé selon la revendication 9 ou 10, dans lequel l'étape de sélection comprend le choix d'un mandrin relativement petit (44) de façon que la surface d'enroulement soit généralement de forme rectangulaire.

13. Procédé selon la revendication 9 ou 10, dans lequel l'étape de sélection comprend le choix d'un mandrin relativement petit (51) de façon que la surface d'enroulement est généralement de forme lenticulaire.

14. Procédé selon la revendication 9 ou 10, dans lequel l'étape de sélection comprend le choix d'un mandrin relativement petit (53) de sorte que la surface d'enroulement est généralement de forme circulaire.

15. Système d'endoprothèse implantable et explantable, comprenant une endoprothèse (31) s'étendant axialement expansible radialement et un dispositif (74) pour explanter transluminalement l'endoprothèse; l'endoprothèse comprend :

une pluralité de sections généralement circonférentielles (32), ces sections généralement circonférentielles étant sensiblement contiguës entre elles et orientées de façon générale axialement l'une par rapport à l'autre pour définir ainsi de façon générale une endoprothèse,
au moins l'une des sections généralement circonférentielles comprend un segment expansible (34) qui confère une expansibilité radiale à la section généralement circonférentielle, cette section ayant une circonférence d'introduction non expansée et une circonférence d'implantation expansée qui est supérieure à la circonférence d'introduction non expansée, et
le segment expansible de la section générale-

ment circonférentielle est un élément généralement pliable qui peut être cintré entre une orientation généralement fermée et une orientation généralement ouverte de façon à conférer une expansibilité radiale à la section généralement circonférentielle (32) ; caractérisé en ce qu'une section extérieure parmi les sections généralement circonférentielles présente une extrémité libre (43) engagée par l'une des sections généralement circonférentielles contiguës ; et

en ce que le dispositif pour explanter transluminalement l'endoprothèse comprend :

un élément allongé (75) qui peut être introduit par voie percutanée dans un vaisseau sanguin (62) ou analogue dans lequel ladite endoprothèse a été radialement expansée et implantée, cet élément allongé ayant une portion proximale extérieure au corps,

des moyens de serre-noeud (77) sur l'extrémité distale de l'élément allongé,

des moyens pour manipuler une portion proximale de l'élément allongé à partir d'un emplacement extérieur au corps, ces moyens de manipulation facilitant l'engagement des moyens de serre-noeud avec l'une des sections circonférentielles de l'endoprothèse implantée,

des moyens d'extraction (78) pour faire coulisser l'élément allongé dans une direction proximale en déplaçant la portion proximale extérieure au corps de l'élément allongé dans une direction l'éloignant de l'endoprothèse,

ce moyen d'extraction étant de plus destiné à réduire la taille radiale de l'endoprothèse à une taille inférieure à la circonférence d'implantation expansée et de façon à pouvoir passer à travers le vaisseau sanguin ou analogue, et

des moyens pour enlever entièrement l'élément allongé du corps jusqu'à ce que l'endoprothèse de taille radiale réduite ait été entièrement explantée.

16. Système selon la revendication 15, dans lequel les sections généralement circonférentielles forment une hélice continue qui définit l'endoprothèse s'étendant axialement et dans lequel le moyen d'extraction est destiné à dérouler cette hélice au moins partiellement.

17. Système selon la revendication 15, dans lequel le moyen d'extraction est destiné à dérouler l'endoprothèse explantée.

18. Système selon la revendication 15, 16 ou 17, comprenant de plus un corps de cathéter (76) à l'intérieur duquel est monté de façon coulissante l'élément allongé.

19. Système selon la revendication 15, 16, 17 ou 18, dans lequel les moyens de serre-noeud comprennent un élément de crochet.

FIG_1_

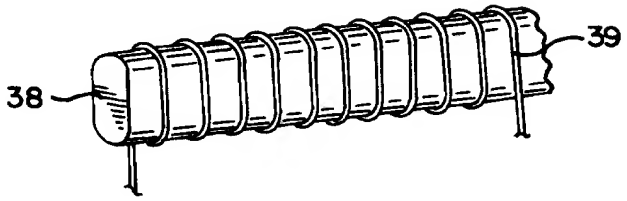


FIG_2_

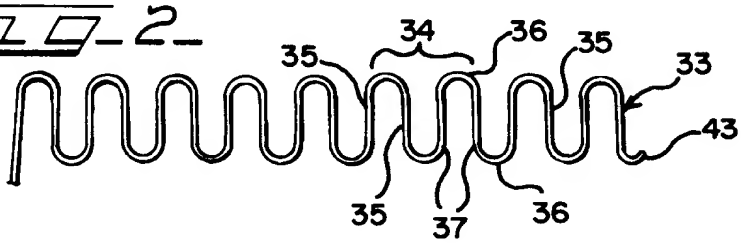


FIG_3_

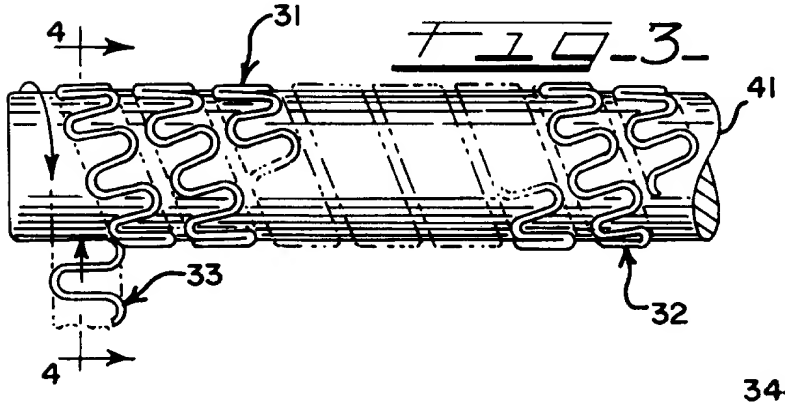


FIG_4_

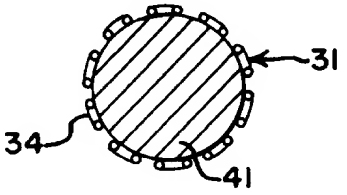


FIG_5_

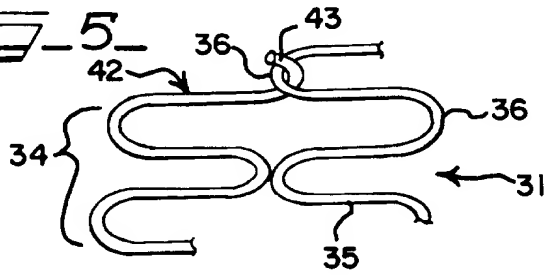


FIG_6_

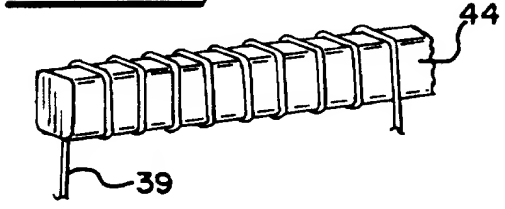


FIG_7_

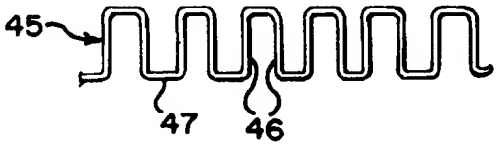


FIG 8

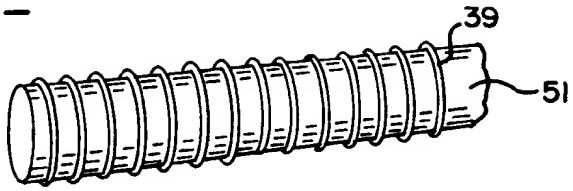


FIG 9

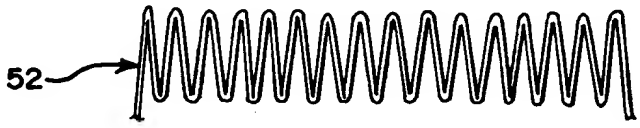


FIG 10

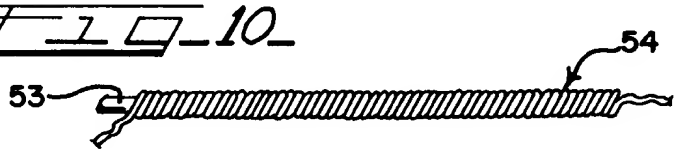


FIG 11

FIG 12

FIG 13

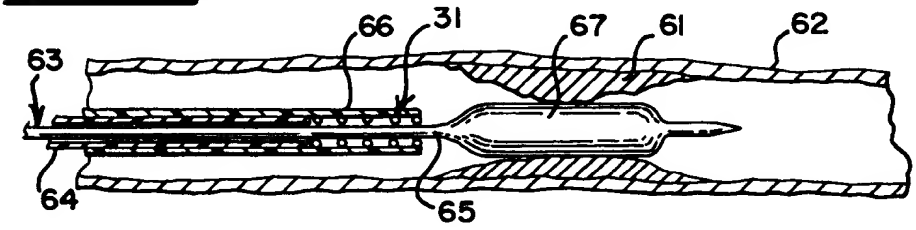


FIG. 14

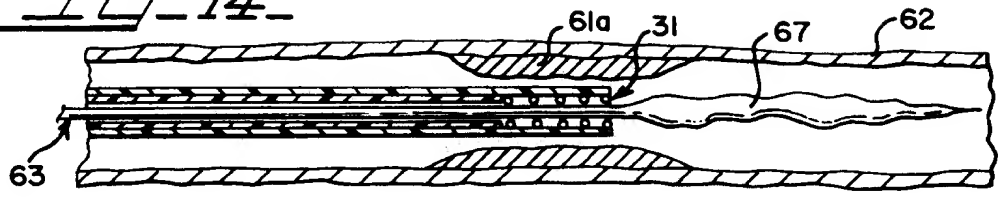


FIG. 15

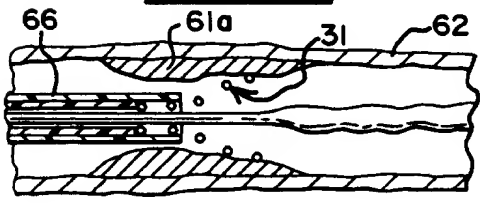


FIG. 16

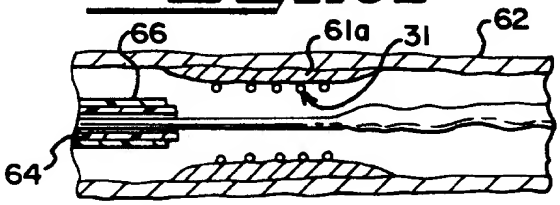


FIG. 17

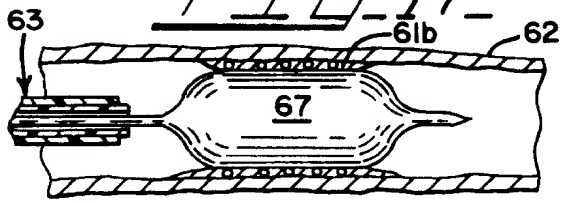
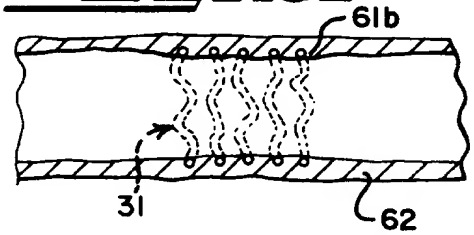


FIG. 18



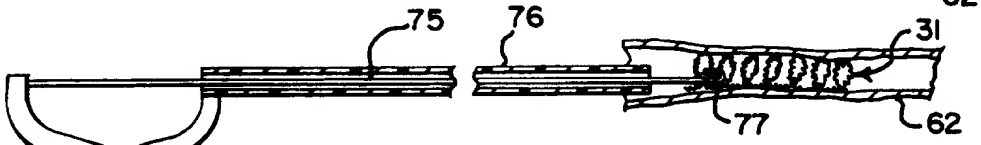
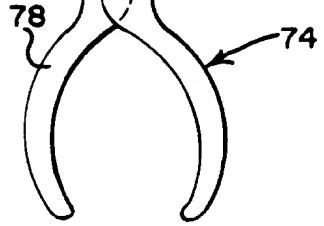


FIG. 24



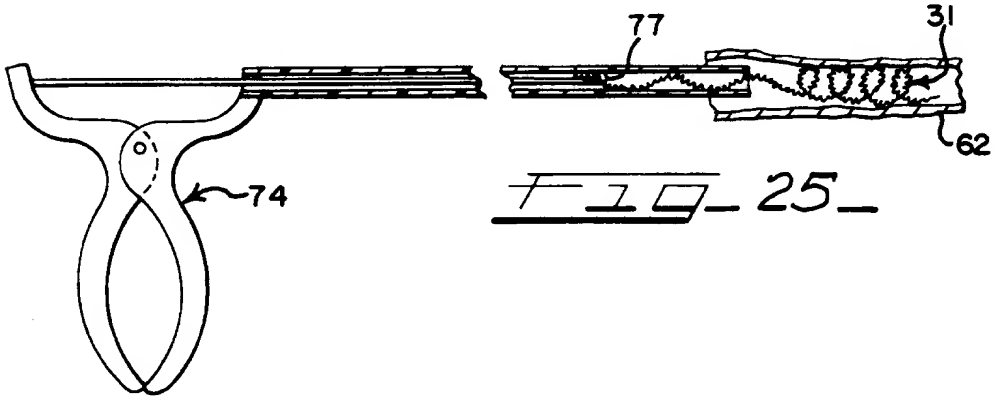


FIG. 25

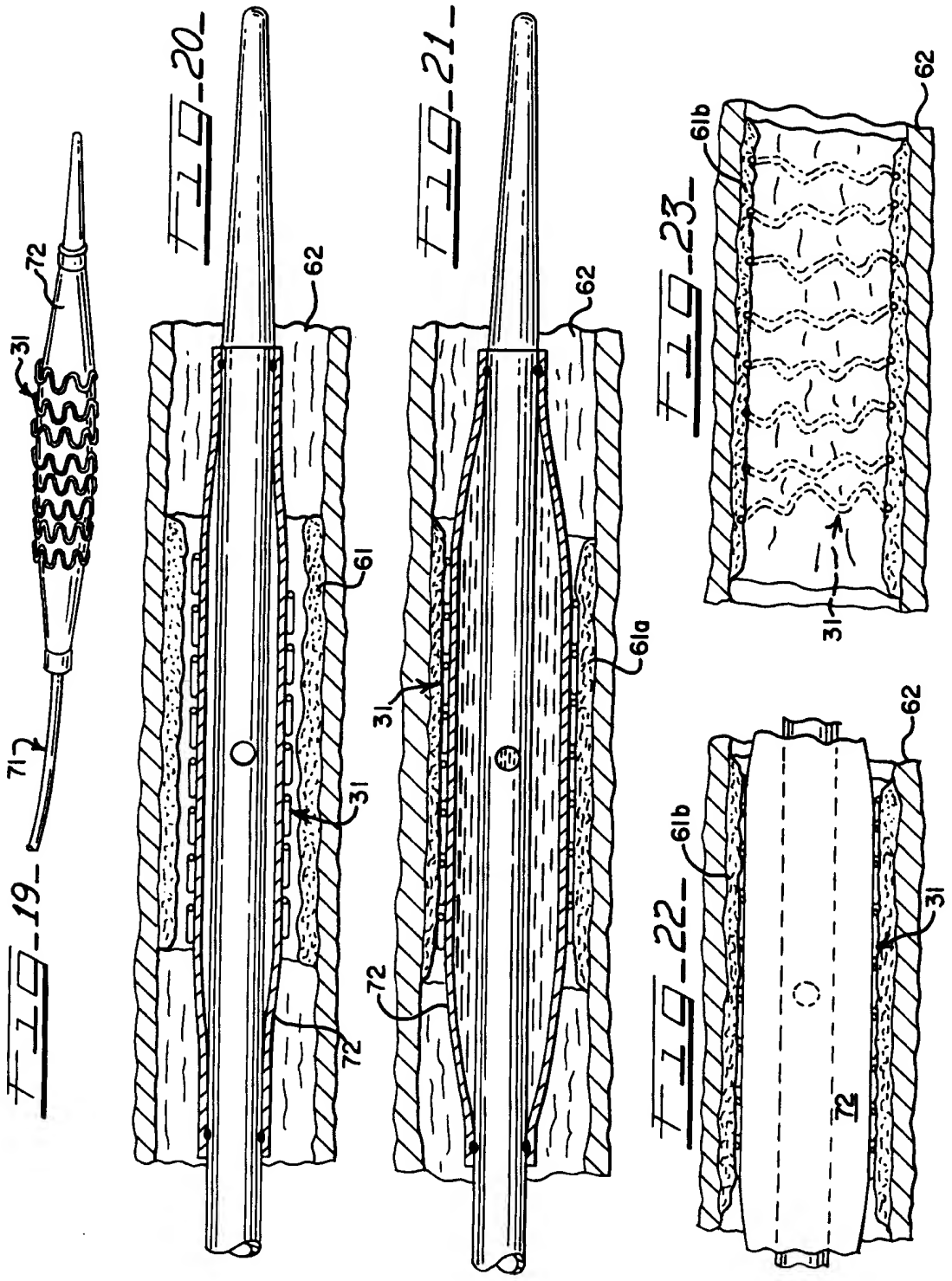


FIG-19
72
31
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FIG-20
62
61
31
72
FIG-21
62
61a
31
72
FIG-23
61b
62
31
FIG-22
61b
62
31
72